Supreme Court, U. S.
FILED
MAY 18 1979
MICHAEL RODAK, JR., CLERK

Nos. 78-911, 78-1036

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

---

BRIEF FOR NATURAL RESOURCES DEFENSE COUNCIL, INC. AS *AMICUS CURIAE*

RICHARD E. AYRES
DAVID D. DONIGER
Attorneys for Natural Resources Defense Council, Inc.
Mailing Address:
NATURAL RESOURCES DEFENSE COUNCIL, INC.
917 15th Street, N.W.
Washington, D.C. 20005
(202) 737-5000

May 17, 1979

INDEX

	Page
INTERESTS OF THE NATURAL RESOURCES DEFENSE COUNCIL	2
QUESTIONS PRESENTED	4
INTRODUCTION AND STATEMENT OF THE CASE	4
A. THE PROBLEM OF OCCUPATIONAL DISEASE	4
B. THE OCCUPATIONAL SAFETY AND HEALTH ACT	7
C. THE BENZENE STANDARD	10
D. THE LOWER COURT DECISION	12
E. SCIENTIFIC AND POLICY ISSUES RELATED TO THE RELIABILITY OF QUANTITATIVE RISK ASSESSMENT AND QUANTITATIVE COST-BENEFIT ANALYSIS	13
1. The Best Available Scientific Knowledge Permits Reliable Identification Of Carcinogens, But Not Reliable Quantification Of Risk	13
a. The Basic Biochemical Process Of Cancer Causation Are Largely Unknown	16
b. Epidemiological Studies Are Capable Of Identifying Carcinogens, But Not The Magnitude Of Cancer Risks	19
c. Animal Experiments Also Permit Identification Of Carcinogens, But Not The Degree Of Risk To Humans	21
2. Techniques For Quantifying Economic Impact	23
3. Comparing Health And Economic Interests	24

Page

SUMMARY OF ARGUMENT 25

ARGUMENT 28

I. THE OCCUPATIONAL SAFETY AND HEALTH ACT DOES NOT REQUIRE QUANTITATIVE JUSTIFICATION FOR STANDARDS TO PROTECT EMPLOYEES FROM CANCER-CAUSING CHEMICALS. 28

A. Conditioning Standards On Quantitative Assessments Of Risk Conflicts With The Congress' Desire To Prevent Disease Before It Develops 31

1. The Primacy Of The Goal Of Preventing Occupationally-Caused Diseases 31

2. Judicial Recognition Of The Primacy Of Preventing Disease 35

B. The Requirement That Standards Be Feasible Does Not Mandate A Quantitative Demonstration That Their Benefits Exceed Their Costs 39

1. The Legislative History Of The Term "Feasible" Shows That Congress Intended Only A Limited Role For Cost Considerations In Setting Standards 40

2. Prior Cases Have Concluded That Costs Are To Be Accorded A Limited Role In Setting Standards 43

C. The Lower Court Erred In Holding That Quantitative Cost-Benefit Analysis Is Mandated By The Requirement That Standards Be "Reasonably Necessary." 48

1. The Legislative History Shows That "Reasonably Necessary" Has No Bearing On The Role Of Cost Considerations 48

Page

2. "Reasonably Necessary" Merely Requires A Rational Connection Between The Means And Objectives of Standards 49

D. The Consumer Product Safety Act Does Not Support The Lower Court's Construction Of The Occupational Safety and Health Act 49

1. The Two Acts Are Not Parallel 50

2. The Consumer Product Safety Act Does Not Require Quantitative Cost-Benefit Analysis 50

II. THE SECRETARY ACTED WELL WITHIN HIS DELEGATED AUTHORITY IN DECLINING TO ADOPT QUANTITATIVE RISK ASSESSMENT 52

A. The Substantial Evidence Test Does Not Permit The Court To Substitute Its Judgment For The Secretary's On The Reliability Of Quantitative Risk Assessments 55

1. Standard Setting Under The Occupational Safety And Health Act Involves A Mixture Of Fact-Finding And Policy-Making 55

2. The Substantial Evidence Test Does Not Prohibit The Secretary From Making Policy Judgments 56

B. The Secretary Reasonably Determined That Quantitative Risk Assessment Techniques Are Not Sufficiently Reliable To Be A Basis For Decision 63

CONCLUSION 67

CITATIONS

	Page
CASES:	
Abbott Laboratories v. *Gardner*, 387 U.S. 136 (1967)	62
AFL-CIO v. *Brennan*, 530 F.2d 109 (3rd Cir. 1975)	12,45,46
American Iron & Steel Inst. v. *OSHA*, 577 F.2d 825 (3rd Cir. (1978), *petition for certiorari pending*	15,37,46, 47,54,60
American Petroleum Inst. v. *OSHA*, 581 F.2d 493 (5th Cir. 1978)	12,13,27, 28,30,37, 38,43,47, 50,54,60, 63,65,66, 67
Arkansas-Best Freight Systems v. *Occ. Safety & Health Rev. Comm'n.* 529 F.2d 649 (8th Cir. 1976)	47
Associated Industries of N.Y.S. v. *United States Dep't of Labor*, 487 F.2d 342 (2d Cir. 1973)	57,60,61
Certified Color Mfrs. Ass'n v. *Mathews*, 543 F.2d 284 (D.C. Cir. 1976)	15,37
Citizens to Preserve Overton Park v. *Volpe*, 401 U.S. 402, (1971)	62
Consolo v. *Federal Maritime Comm'n* 383 U.S. 607 (1966)	62
Environmental Defense Fund v. *EPA*, —F.2d—, 8 ELR 20765 (D.C. Cir. 1978)	15,37,39
Environmental Defense Fund v. *EPA*, 510 F.2d 1291 (D.C. Cir. 1975)	15,37
Federal Communications Comm'n v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, (1978)	59
Florida Peach Growers Ass'n v. *United States Dep't of Labor*, 489 F.2d 120, 129 (5th Cir. 1974)	60

	Page
Industrial Union Dep't, AFL-CIO v. *Hodgson*, 499 F.2d 467 (D.C. Cir. 1974);	12,15,35, 44,47,54, 57,58,59, 60,61,62, 63
National Nutritional Foods Ass'n v. *Weinberger*, 512 F.2d 688 (2d Cir. 1975),	61
Permian Basis Area Rate Cases, 390 U.S. 747 (1968)	58
Society of the Plastics Industry v. *OSHA*, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975)	15,35,45, 54,60
Synthetic Organic Chemical Mfrs. Ass'n v. *Brennan*, 503 F.2d 1155 (3rd Cir. 1974)	15,35,54, 60
Universal Camera Corp. v. *NLRB*, 340 U.S. 474 (1950)	62
STATUTES:	
Occupational Safety and Health Act of 1970	
Section 2, 29 U.S.C. §651	5
Section 3, 29 U.S.C. §652	*passim*
Section 6, 29 U.S.C. §655	*passim*
Section 20, 29 U.S.C. §669	10
Section 21, 29 U.S.C. §670	10
Section 22, 29 U.S.C. §671	10
Consumer Product Safety Act of 1972	
Section 7, 15 U.S.C. §2056	50, 59
Section 9, 15 U.S.C. §2058	50
Section 11, 15 U.S.C. §2060	59
Toxic Substances Control Act of 1976	
Section 4, 15 U.S.C. §2603	14
Section 6, 15 U.S.C. §2605	59
Section 19, 15 U.S.C. §2618	59
Clean Air Act Amendments of 1977	
Section 307, 42 U.S.C. §7607	62

Page

REGULATIONS AND REGULATORY NOTICES:
Federal Regulations
29 C.F.R. §1910. 1000 8
29 C.F.R. §1910. 1028 10
Federal Register Statements
43 Fed. Reg. 5918 (1978) 8, 10, 11, 12, 19, 20, 63, 64
42 Fed. Reg. 54,148 (1977) 15
42 Fed. Reg. 26,429 (1977) 8
41 Fed. Reg. 46,742 (1976) 24, 63
41 Fed. Reg. 21,402 (1976) 15
36 Fed. Reg. 10,466 (1976) 8

LEGISLATIVE HISTORY:
Occupational Safety and Health Act of 1970
Subcommittee on Labor of the Senate Committee on Labor and Public Welfare, Legislative History of the Occupational Safety and Health Act of 1970 (1971) 32, 41, 42, 43, 48
S. Rep. No. 1282, 91st Cong., 2d Sess. (1970) 4, 5, 6, 7, 8, 33, 34, 41, 42, 43, 49
H.R. Rep. No. 1291, 91st Cong., 2d Sess. (1970) 11, 32, 34, 35, 38, 40, 42, 43
Consumer Product Safety Act of 1972
H.R. Rep. No. 1153, 92nd Cong., 2d Sess. (1972) 50, 51

Page

Toxic Substances Control Act of 1976
H.R. Rep. No. 1341, 94th Cong., 2d Sess. (1976) 51, 52, 59
Clean Air Act Amendments of 1977
H.R. Rep. No. 564, 95th Cong., 1st Sess. (1977) 62

MISCELLANEOUS:
Baram, *Regulation of Health, Safety And Environmental Quality And The Use of Cost-Benefit Analysis*, Final Report to the Administrative Conference of the United States (1979) 25
Boyland, *The Correlation of Experimental Carcinogenesis and Cancer in Man*, 11 PROGRESS IN EXPERIMENTAL TUMOR RESEARCH 222 (1969) 7
BRAUN, THE BIOLOGY OF CANCER (1974) 17
Bridbord, Decoufle, Fraumeni, Hoel, Hoover, Rall, Saffiotti, Schneiderman & Upton, *Estimates of the Fraction of Cancer in the United States Related to Occupational Factors* (U.S. HEW 1978) 7
Cairns, *The Cancer Problem*, SCIENTIFIC AMERICAN November 1975, at 64 6
Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693 (1977) 22
COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT (1975) 6, 20
Crump, Hoel, Langley & Peto, *Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2973 (1976) 17
DOLL, PREVENTION OF CANCER: POINTERS FROM EPIDEMIOLOGY (1967) 7
EPA Carcinogen Assessment Group, Final Report on Population Risk to Ambient Benzene Exposures (with cover memorandum dated January 10, 1979) 65

Page

Epstein, *Environmental Determinants of Human Cancer*, 34 CANCER RESEARCH 2425 (1974) 7

Fischhoff, *Cost-Benefit Analysis and the Art of Motorcycle Maintenance*, ~~45 POLICY ANALYSIS 64 (1978)~~ 8 Policy Sciences 177 (1977) 25

FRAUMENI (Ed.), PERSONS AT HIGH RISK OF CANCER, AN APPROACH TO ETIOLOGY AND CONTROL 7, 14, 18

FRIENDLY, *"Some Kind of Hearing,"* 123 U. Penn. L. Rev. 1267, 1313-14 (1975) 61

GOLDSTEIN, ARONOW & KALMAN, PRINCIPLES OF DRUG ACTION: THE BASIS OF PHARMACOLOGY (2d ed. 1974) 18

Goodrich Cuts Cost of Meeting VCM Limits, CHEMICAL WEEK, Dec. 10, 1975 24

Greek, *Vinyl Chloride May Force Shortages by 1977*, CHEM. & ENGINEERING NEWS, Aug. 11, 1975 24

HIATT, WATSON & WINSTEN (Eds.), ORIGINS OF HUMAN CANCER (1977) 14, 21

Higginson, *Importance of Environmental Factors in Cancer*, in ENVIRONMENTAL POLLUTION AND CARCINOGENIC RISKS 15, (C. Rosenfield & W. Davis, eds. 1975) 7

Hoover, *Detection of Environmental Cancer Hazards: Epidemiological Methods*, 75 J. OF THE MEDICAL SOC. OF N.J. 746 (1978) 14, 20

Infante, Wagoner, Rinsky & Young, *Leukemia in Benzene Workers*, THE LANCET, July 9, 1977, at 76 10

INTERNATIONAL UNION AGAINST CANCER (UICC) CARCINOGENICITY TESTING: A REPORT OF THE PANEL ON CARCINOGENICITY OF THE CANCER RESEARCH COMM'N (1969) 14

Kramer & Mutchler, *The Correlation of Clinical and Environmental Measurements For Workers Exposed to Vinyl Chloride*, 33 AM. INDUS. HYGIENE ASS'N J. 19 (1972) 20

Page

Mancuso, *Comments for Opening of Discussion of "Neoplastic Effects,"* 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 251 (1975) 14

Mantel & Schneiderman, *Estimating "Safe" Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH 1379 (1975) 21

MINISTRY OF HEALTH & WELFARE (CANADA), THE TESTING OF CHEMICALS FOR CARCINOGENICITY, MUTAGENICITY, AND TERATOGENICITY (1975) 14

NATIONAL ACADEMY OF SCIENCES, AN EVALUATION OF THE CARCINOGENICITY OF CHLORDANE AND HEPTACHLOR (1977) 14, 18

NATIONAL ACADEMY OF SCIENCES, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT (1975) 52

NATIONAL ACADEMY OF SCIENCES, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY (1977) 23, 24

NATIONAL ACADEMY OF SCIENCES, DRINKING WATER AND HEALTH (1977) 14, 18, 19

NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT (1975) 14

NATIONAL ACADEMY OF SCIENCES, SACCHARIN: TECHNICAL ASSESSMENT OF RISKS AND BENEFITS (1978) 15, 22, 23

OFFICE OF TECHNOLOGY ASSESSMENT (U.S. CONGRESS), CANCER TESTING TECHNOLOGY AND SACCHARIN (1977) 14

PVC Rolls Out of Jeopardy, Into Jubilation, CHEMICAL WEEK, Sept. 15, 1976 24

Rall, *Problems of Low Doses of Carcinogens*, 64 J. WASH. ACAD. SCI. 63 (1974) 22

REPORT OF THE SECRETARY'S COMMISSION ON PESTICIDES AND THEIR RELATIONSHIP TO ENVIRONMENTAL HEALTH (U.S. HEW 1969) 14

Page

REPORT OF THE SURGEON GENERAL'S AD HOC COMMITTEE ON THE EVALUATION OF LOW LEVELS OF ENVIRONMENTAL CARCINOGENS (1970) ... 14, 18

ROWE, AN ANATOMY OF RISK (1977) ... 23

Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. REV. 899 (1973) ... 62

Schneiderman, Decoufle & Brown, *Thresholds for Environmental Cancer: Biological and Statistical Considerations*,—ANNALS OF THE N.Y. ACADEMY OF SCIENCES—(in press) ... 18

Schneiderman, Mantel & Brown, *From Mouse to Man—Or How to Get From the Laboratory to Park Avenue and 53rd Street*, 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 237 (1975) ... 72

Tomatis, Agthe, Bartsch, Huff, Montesand, Saracci, Walker & Wilburn, *Evaluation of the Carcinogenicity of Chemicals: A Review of the Monograph Program of the International Agency for Research in Cancer*, 38 CANCER RESEARCH 877 (1978) ... 21

Upton, Speech to American Cancer Society Science Writers' Seminar, Mar. 25-28, 1979 ... 16

URBAN ENVIRONMENT CONFERENCE (Eds.), ENVIRONMENTAL CANCER: CAUSES, VICTIMS, SOLUTIONS (1968) ... 14, 20

Weinstein, Yamaguchi, Gebert & Kaighn, *Use of Epithelial Cell Cultures for Studies on the Mechanism of Transformation by Chemical Carcinogens*, 11 IN VITRO 130 (1975) ... 17

Weisburger, *Chemical Carcinogens*, in TOXICOLOGY 333 (Casarett & Doull eds. 1975) ... 17, 18

WORLD HEALTH ORGANIZATION, EVALUATION OF THE CARCINOGENIC HAZARDS OF FOOD ADDITIVES, Technical Report No. 220 (1961) ... 14

WORLD HEALTH ORGANIZATION, PREVENTION OF CANCER, Technical Report No. 276 (1974) ... 7

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents;

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR
Petitioner,

v.

AMERICAN PETROLEUM INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

---

BRIEF FOR NATURAL RESOURCES DEFENSE COUNCIL, INC. AS *AMICUS CURIAE*

INTEREST OF *AMICUS CURIAE* NATURAL RESOURCES DEFENSE COUNCIL

The Natural Resources Defense Council, Inc. ("NRDC")—a national environmental organization with more than 44,000 members residing in all states and territories, as well as abroad—has as one of its principle objectives the prevention of environmentally-caused disease. The prevention of cancer caused by exposure to man-made chemicals is among the highest of NRDC's priorities, in view of the fact that it is responsibly estimated that the majority of the cases of this dreaded disease are caused by such chemicals.

In pursuit of this objective, NRDC closely monitors the development of federal cancer policies in the Department of Labor, the Environmental Protection Agency, and other federal agencies that are responsible for protecting the public from exposure to cancer-causing substances in the workplace and general environment. Recently, for example, NRDC submitted detailed scientific and policy comments on the proposed general cancer policy of the Department of Labor. NRDC has also played a similar role in the development of the general cancer policies of the Environmental Protection Agency and the Food and Drug Administration.

NRDC has also played an important part in a number of administrative proceedings relating to specific toxic substances with carcinogenic properties. NRDC was among the first to call to the government's attention the scientific evidence that synthetic fluorocarbons damage the stratospheric ozone layer, which protects the world's people from solar radiation that causes skin cancer. This evidence later become the basis for executive and legislative actions to limit nonessential uses of fluorocarbons. NRDC also brought to the attention of the Food and Drug Administration the potential cancer-causing properties of

certain kinds of plastic soft drink bottles, which that agency has since decided should not be used.

In the Occupational Safety and Health Act, and a number of other major laws, the Congress of the United States has responded to the growing national concern over the rapid increase in, and grim results of, exposure to cancer-causing substances. NRDC and its members have a substantial interest in preserving the integrity of these laws, in view of the importance of environmental factors in causing cancer. In addition, NRDC and its members have an interest in the outcome of this case because the basic legal issues presented here permeate the entire body of the Congressional enactments to control the incidence of cancer. This Court will provide an authoritative interpretation of the Occupational Safety and Health Act, which will affect as well the many other federal laws designed to reduce the toll from cancer.

Regarding the issues presented here, NRDC believes the Secretary properly interpreted the Occupational Safety and Health Act when he concluded that it committed to his discretion the question whether quantifying the magnitude of the risk of cancer-causing substances, and balancing the costs and benefits of proposed regulations, could be done with sufficient precision to provide useful guidance in establishing the preventive standards required by the Act. In addition, we believe the Secretary properly exercised this discretion when he concluded that these techniques were too immature to inform his judgment meaningfully. As discussed in this brief, we agree with the Secretary that quantitative risk assessment, and cost-benefit analysis, are now too primitive to be thrust into the prominent role envisioned by the court below. If the objectives of the law are to be achieved, it is essential that this Court uphold the Secretary's authority to act to prevent cancer on the basis of the best available evidence, rather than forcing the public to wait for the development

of a degree of precision that is, at least at present, beyond the capabilities of science.

All parties to both cases consented to the filing of a brief by NRDC as *amicus curiae*. Copies of the letters of consent are filed with this brief.

QUESTIONS PRESENTED

1. Whether the Occupational Safety and Health Act provides authority for the Secretary of Labor to limit employees' exposure to carcinogenic chemicals to the extent feasible on the basis of qualitative evidence that they cause cancer, rather than requiring him to withhold regulation until he has information sufficiently detailed to permit quantitative assessment of the magnitude of the health risk, and until he performs a quantitative cost-benefit analysis of contemplated standards.

2. Whether the Secretary acted within his discretion when he determined that the techniques of quantitative risk assessment and cost-benefit analysis would not usefully sharpen his judgment in establishing a standard to prevent cancer induced by workplace exposure to benzene.

INTRODUCTION AND STATEMENT OF THE CASE

A. The Problem of Occupational Disease.

In 1970, Congress determined that the devastating toll of deaths, illnesses and injuries caused in American workplaces must be drastically reduced. Occupational accidents alone then claimed more than 14,500 lives and disabled at least 2.2 million people each year.[1] Each year chemicals and dusts in the workplace caused at least

[1] S. REP. NO. 1282, 91st Cong., 2 Sess. 2 (1970) [hereinafter cited as SENATE REPORT].

390,000 new cases of occupational illness.[2] Congress concluded that the engine of American prosperity had to be made safer for those who operated it. To this end Congress enacted the Occupational Safety and Health Act,[3] whose primary purpose is "to assure so far as possible every working man and woman in the Nation safe and healthful employment and places of employment."[4]

The legislators set special emphasis on controlling the careless use of toxic substances in the workplace, which are causing cancer, respiratory and heart diseases, nervous disorders, sterility and other killing and disabling diseases. The Senate and House Committees cited chemical dangers running the gamut from the "ancient" poisons such as lead and mercury to the newest exotic products of the Petrochemical Age:

> [M]aterials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, ultrasonic energy, beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and

[2] *Id.* at 3. The Committee stated: "In the field of occupational health, the view is particularly bleak, and, due to the lack of information and records, may well be considerably worse than we know." *Id.* at 2.

[3] PUB. L. NO. 91-596, 84 Stat. 1591 (codified at 29 U.S.C. §§ 651-678).

[4] *Id.* §2(b), 29 U.S.C. §651(b).

> potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.[5]

Congress took especially seriously the developing edge of scientific knowledge showing alarming trends in occupationally induced disease:

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.[6]

Since 1970, these findings and predictions have been amply borne out.

The chemical hazard most on the public's and Congress' mind, then and now, is cancer. One American in four will contract some form of cancer; one in five is expected to die from it.[7] The concensus of scientific experts is that the majority of cancer is caused by exposure to

[5] SENATE REPORT, *supra* note 1, at 2.

[6] *Id.*

[7] COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT 12 (1975); Cairns, *The Cancer Problem*, SCIENTIFIC AMERICAN November 1975, at 66.

chemical substances.[8] At least a fifth—perhaps a third or more—of all cancer in the United States is related to chemicals in the workplace.[9] A grim list of specific occupational chemicals has been identified as carcinogenic and continues to grow.[10] Benzene, which causes leukemia, is one such substance.

B. The Occupational Safety and Health Act

The Occupational Safety and Health Act authorizes the Secretary of Labor to set standards to protect employees from toxic substances. The Act provides for three kinds of standards for such substances. As an interim measure, section 6 (a) of the Act directed the Secretary by 1972 to promulgate as federally enforceable standards any existing "national consensus standards."[11] These are safety and health standards developed before 1970, generally by industry-funded organizations, and voluntarily agreed to by individual companies.[12] In 1971 the Secretary

[8] World Health Organization, Prevention of Cancer, Technical Report No. 276 (1974); Higginson, *Importance of Environmental Factors in Cancer in* ENVIRONMENTAL POLLUTION AND CARCINOGENIC RISKS 15, 17 (C. Rosenfield & W. Davis, eds. 1975); Boyland, *The Correlation of Experimental Carcinogenesis and Cancer in Man*, 11 PROGRESS IN EXPERIMENTAL TUMOR RESEARCH 222, 223 (1969); Epstein, *Environmental Determinants of Human Cancer*, 34 CANCER RESEARCH 2425 (1974). *See also* R. DOLL, PREVENTION OF CANCER: POINTERS FROM EPIDEMIOLOGY (1967).

[9] Bridbord, Decoufle, Fraumeni, Hoel, Hoover, Rall, Saffiotti, Schneiderman & Upton, *Estimates of the Fraction of Cancer in the United States Related to Occupational Factors* (U.S. HEW 1978).

[10] *See* Cole & Goldman, *Occupation*, in PERSONS AT HIGH RISK OF CANCER, AN APPROACH TO ETIOLOGY AND CONTROL 167 (1975). [hereinafter cited as PERSONS AT HIGH RISK OF CANCER].

[11] 29 U.S.C. §655(a).

[12] SENATE REPORT, *supra* note 1, at 5-6.

adopted some 400 such standards for air contaminants, including the existing 10 parts per million (ppm) standard for benzene.[13] These standards merely codified contemporary industry self-regulation. Generally they were set at levels necessary to prevent only the acute and chronic effects of moderately high exposures. They were not designed to protect against the long-term adverse effects of lower doses, which largely had not been investigated. This was the case for the benzene standard, which was aimed only at some of the chemical's nonmalignant effects.[14] The Senate and House Committees made clear that national consensus standards were not substitutes for more protective standards when further research demonstrated the need.[15]

Section 6(c) empowers the Secretary to set without rule-making "emergency temporary standards" when necessary to protect employees from "grave danger" due to new or newly discovered hazards.[16] These are effective immediately upon promulgation, and must be replaced by so-called "permanent" standards within six months, which must be developed through normal rulemaking procedures.[17] In May 1977, The Secretary promulgated an emergency temporary standard of one ppm for benzene upon concluding that it causes leukemia.[18]

---

[13] 36 Fed. Reg. 10,466 (1971), codified in 29 C.F.R. §1910.1000 table Z-1.

[14] 43 Fed. Reg. 5919 (1978) (preamble to the Secretary's benzene standard).

[15] SENATE REPORT, *supra* note 1, at 6; H.R. REP. NO. 1291, 91st Cong., 2d Sess. 17 (1970) [hereinafter cited as HOUSE REPORT].

[16] Occ. Safety & Health Act §6(c)(1), 29 U.S.C. §655(c)(1).

[17] *Id.* §6(c)(2)-(3), 29 U.S.C. §655(c)(2)-(3).

[18] 42 Fed. Reg. 26429 (1977). The standard never became effective. It was stayed by the Fifth Circuit, American Petroleum Inst. v. OSHA, No. 77-1516 (stay ordered, May 20, 1977), and the case was rendered moot by the promulgation of the final standard and the judicial challenge here under review.

The main vehicle for protecting employees from toxic substances is the so-called "permanent standard," established under Section 6(b), the provision at issue in this litigation.[19] This Act sets out the criteria for such standards in the detailed provisions of Section 6(b)(5). The Secretary must set the standard for such a substance

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.[20]

Section 6(b) provides for informal rulemaking, supplemented by an opportunity for a public hearing.[21] Section 6(e) requires the Secretary to give a statement of reasons with each standard.[22] Section 6(f) provides for pre-enforcement review of such standards in the Courts of Appeals; the court must uphold the Secretary's determinations if they are supported by substantial evidence.[23]

---

[19] 29 U.S.C. §655(b).

[20] *Id.* §655(b)(5).

[21] *Id.* §655(b)(1)-(4).

[22] *Id.* §655(e).

[23] *Id.* §655(f).

C. The Benzene Standard

The Secretary promulgated a section 6(b)(5) permanent standard for benzene in February 1978, after extensive comment and hearings.[24] The standard reduced the permissible benzene exposure from 10 parts per million ("ppm") to one ppm.[25] The Secretary accompanied the standard with a detailed statement of the reasons for this reduction. He based the requirement both on benzene's clearly demonstrated leukemogenicity and on its capacity to cause a wide variety of non-malignant disorders of the blood-forming system. The most recent study was by the National Institute for Occupational Safety and Health,[26] of employees in Ohio exposed to benzene in the manufacture of Pliofilm.[27] The study showed at least a five-fold excess of leukemia over the unexposed population in these workers.[28] The Secretary concluded that because benzene was a carcinogen, a safe level of exposure could not be demonstrated. Finally, he concluded that the reduction to one ppm would produce "appreciable" health benefits, in terms of reduced risk of both cancer and other benzene-induced disease.[29]

Facing a life-threatening substance for which no safe level of exposure could be established, he determined that under section 6(b)(5) he must reduce benzene exposure to "the extent feasible."[30] After carefully estimating the

[24] 43 Fed. Reg. 5918 (1978), 29 C.F.R. §1910.1028.

[25] 29 C.F.R. §1910.1028(c).

[26] The Occupational Safety and Health Act established NIOSH as an institute in the National Institutes of Health, under the Department of Health, Education and Welfare, and gives it duties to perform research and to aid the Secretary in setting standards. Occ. Safety & Health Act §§20-22, 29 U.S.C. §§669-671.

[27] Infante, Wagoner, Rinsky & Young, *Leukemia in Benzene Workers*, THE LANCET, July 9, 1977, at 76.

[28] *Id.*

[29] 43 Fed. Reg. 5940 (1978).

[30] *Id.* at 5934, 5940-41.

total costs of compliance by the industries making and using benzene, the Secretary concluded that a permissible exposure level of one part per million was feasible, as, even under the industries' cost assumptions, "the economic impact of the final benzene standard will not be such as to threaten the financial welfare of the affected firms or the general economy."[31]

The Secretary rejected the claims—then raised under the rubric of "feasibility"—that prior to setting a standard to protect employees from an undisputed carcinogen, he must quantify the cancer risk reduction the standard would achieve and show through a quantitative cost-benefit analysis that the standard's health benefits outweighed its economic costs. For reasons detailed below, he concluded that techniques do not exist to quantify risks with accuracy and reliability necessary to be of use to him in making his decision.[32] Moreover, he concluded that no basis exists to determine the value of life and health in dollars, so that no objective method of conducting a quantitative cost-benefit analysis existed. Neither form of quantitative analysis would "significantly clarify the ultimate decision."[33]

The Secretary observed that the Occupational Safety and Health Act does not require him to delay regulation of known cancer-causing substances until precise quantitative knowledge of the number of cancers that will occur at particular doses can be established.

Rather, he stated that he must act now to protect the employees from known causes of killing and disabling illness. As the House Report stated, he must act on the basis of the best available evidence and must not be "paralyzed by debate surrounding diverse medical opinions."[34] When facing a life-threatening substance for

[31] *Id.* at 5939.

[32] *Id.* at 5940-41.

[33] *Id.*

[34] HOUSE REPORT, *supra* note 15, at 18.

which no safe dose can be determined, the Secretary determined that the Act directs him to reduce employee exposure to the extent feasible. Citing prior cases,[35] he concluded that a standard which closed whole industries or forced a substantial fraction of employers in an industry out of business would not be feasible. But short of this drastic result, he concluded employees are entitled by the Act to protection from such hazards.[36]

D. The Lower Court Decision

The American Petroleum Institute and other trade organizations and individual companies sought review of the standard in the United States Court of Appeals for the Fifth Circuit. The court vacated the standard in October 1978.[37]

The lower court decision held, for the first time, that in setting a standard under section 6(b)(5) for an undisputed carcinogen, the Secretary must quantify the health benefits the standard would provide and show through a quantitative cost-benefit analysis that the benefits bear a "reasonable relationship" to the costs. The court based this holding not on the requirement that achieving the standard be "feasible" as required by Section 6(b)(5), but on Section 3(8), which defines an occupational safety and health standard as a standard "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[38] As additional bases for the court's conclusion that the Secretary must have quantitative knowledge of the size of cancer risks at particular doses before he may set a standard, the court pointed to four phrases in Section 6(b)(5)—"the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws."[39]

Finally, although the court conceded the Secretary had acted rationally, it held the Secretary's conclusion that "appreciable" health benefits would flow from the standard not to be supported by substantial evidence. The court held that substantial evidence could be provided only by a quantitative assessment of the risks.[40]

E. Scientific and Policy Issues Related to the Reliability of Quantitative Risk Assessment and Quantitative Cost-Benefit Analysis

A correct appraisal of the requirements of the Act and the reasonableness of the Secretary's actions depends on a firm understanding of the techniques of risk assessment and quantitative benefit analysis. Weighing the costs and benefits of a proposed regulation of the sort under review requires being able to quantify the magnitude of the health and economic interests at stake, and to know the appropriate way to balance them.

1. *The Best Available Scientific Knowledge Permits Reliable Identification of Carcinogens, But Not Reliable Quantification of Risk*

The main tools for identifying chemicals that cause cancer are studies of exposed human populations (epide-

[35] Industrial Union Dep't AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); AFL-CIO v. Brennan, 530 F.2d 109 (3rd Cir. 1975).

[36] 43 Fed. Reg. 5934 (1978).

[37] American Petroleum Inst. v. OSHA, 581 F.2d 493 (5th Cir. 1978).

[38] *Id.* at 502-03; 29 U.S.C. §652(8).

[39] 581 F.2d at 504; Occ. Safety & Health Act §6(b)(5), 29 U.S.C. §655(b)(5).

[40] 581 F.2d at 503.

miology)[41] and laboratory studies on animals.[42] These techniques provide a well-recognized basis for identifying chemicals posing carcinogenic risk for humans. The validity of these techniques has been confirmed repeatedly for two decades by expert scientists and scientific institutions.[43] They have been accepted by Congress,[44] the

[41] Hoover, *Detection of Environmental Cancer Hazards: Epidemiological Methods*, 75 J. OF THE MEDICAL SOC. OF N.J. 746 (1978) [hereinafter cited as Hoover]; Hoover, *Cancer Epidemiology*, in ENVIRONMENTAL CANCER: CAUSES, VICTIMS, SOLUTIONS 4 (1978) [hereinafter cited as ENVIRONMENTAL CANCER]; Mancuso, *Comments for Opening of Discussion of "Neoplastic Effects,"* 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 251 (1975) [hereinafter cited as Mancuso]. *See generally* articles in PERSONS AT HIGH RISK OF CANCER, *supra* note 10, and in ORIGINS OF HUMAN CANCER, Book A (Hiatt, Watson, & Winsten eds. 1977) [hereinafter cited as ORIGINS OF HUMAN CANCER].

[42] CARCINOGENICITY TESTING, A REPORT OF THE PANEL ON CARCINOGENICITY OF THE CANCER RESEARCH COMM'N, INTERNATIONAL UNION AGAINST CANCER (UICC) (1969); Saffiotti, *Identifying and Defining Chemical Carcinogens*, in ORIGINS OF HUMAN CANCER, *supra* note 41, Book C, at 1311.

[43] *E.g.*, REPORT OF THE SURGEON GENERAL'S AD HOC COMMITTEE ON THE EVALUATION OF LOW LEVELS OF ENVIRONMENTAL CARCINOGENS (1970), *reprinted in Chemicals and the Future of Man, Hearings before the Subcomm. on Executive Reorganization and Government Research of the Senate Comm. on Government Operations*, 92d Cong., 1st Sess. 180 (1971). [hereinafter cited as SURGEON GENERAL'S REPORT]; NATIONAL ACADEMY OF SCIENCES, DRINKING WATER AND HEALTH 29-59 (1977) [hereinafter cited as DRINKING WATER AND HEALTH]; OFFICE OF TECHNOLOGY ASSESSMENT (U.S. CONGRESS), CANCER TESTING TECHNOLOGY AND SACCHARIN (1977); NATIONAL ACADEMY OF SCIENCES, AN EVALUATION OF THE CARCINOGENICITY OF CHLORDANE AND HEPTACHLOR (1977) [hereinafter cited as NAS CHLORDANE/HEPTACHLOR EVALUATION]; NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT (1975); MINISTRY OF HEALTH & WELFARE (CANADA), THE TESTING OF CHEMICALS FOR CARCINOGENICITY, MUTAGENICITY, AND TERATOGENICITY (1975); REPORT OF THE SECRETARY'S COMMISSION ON PESTICIDES AND THEIR RELATIONSHIP TO ENVIRONMENTAL HEALTH (U.S. HEW 1969). For an early report reaching these conclusions, *see* World Health Organization, Evaluation of the Carcinogenic Hazards of Food Additives, Technical Report No. 220 (1961).

[44] *See e.g.*, Toxic Substances Control Act, §4, 15 U.S.C. §2603, which requires testing for carcinogenicity, among other effects.

agencies,[45] and the Courts of Appeals[46] as a valid basis for preventive regulation.

But at this time these techniques do not permit reliable quantification of human risk, particularly at and below levels to which employees are currently exposed. Even where a qualitative causal relationship is clearly visible, as is the case for benzene, reliable quantitative risk estimates for humans cannot be made. For a given substance the risk estimates from equally respected quantitative models—each based on different plausible assumptions about how chemicals cause cancer—differ by a factor of 5,000,000 or more.[47]

Facts such as these have led some of the nation's leading scientific experts in cancer cause and prevention to conclude that quantitative risk assessment (and thus cost-benefit balancing) are not useful aids to standard-setting at this point. Dr. Arthur C. Upton, who is Director of the nation's anti-cancer program at the National

[45] See *e.g.*, the Secretary's Proposed Carcinogen Policy, 42 Fed. Reg. 54,148 (1977), and the Environmental Protection Agency's Interim Carcinogen Policy, 41 Fed. Reg. 21,402 (1976).

[46] *See e.g.*, Environmental Defense Fund v. EPA, —F.2d—, 8 ELR 20765 (D.C. Cir. 1978) (PCBs, toxic water pollutants); American Iron & Steel Inst. v. OSHA, 577 F.2d 825 (3rd Cir. 1978) (coke oven emissions); Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975) (vinyl chloride); Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3rd Cir. 1974) (ethyleneimine); Industrial Union Dep't AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974) (asbestos); Certified Color Mfrs. Ass'n v. Matthews, 543 F.2d 284 (D.C. Cir. 1976) (food color additives); Environmental Defense Fund v. EPA, 510 F.2d 1291 (D.C. Cir. 1975) (pesticides aldrin/dieldrin).

[47] NATIONAL ACADEMY OF SCIENCES, SACCHARIN: TECHNICAL ASSESSMENT OF RISKS AND BENEFITS 3-72, Table 3-8 (1978) [hereinafter cited as NAS SACCHARIN STUDY].

Cancer Institute, summarized their conclusions recently as follows:

> Based on current scientific knowledge it is not possible to accurately calculate risks for most substances. Various recently developed statistical methods attempt to extrapolate from animal data to human risk, thereby computing an estimate of how many persons in a given population can be expected to get cancer from a given dosage of a particular carcinogen. But the process has severe limitations.
>
> . . .
>
> We have the scientific means to identify substances which cause cancer in animals and which are, therefore, potential carcinogens for humans. There is as yet, however, no scientific way to arrive at quantitative and precise risk estimates for humans based on extrapolating from animal data and, therefore no scientific basis for accurately and confidently weighing the benefits of a particular substance against its risks as a potential carcinogen.[48]

The basic biochemical mechanisms of chemically-induced cancer are as complicated as life itself. They are not adequately understood, and the uncertainties will undoubtedly be removed only through years of research, depending largely on unpredictable, serendipitous insight. In the interim, however, we have the means to identify qualitatively many carcinogenic chemicals.

a. *The Basic Biochemical Processes of Cancer Causation are Largely Unknown*

The biological mechanism by which chemicals cause cancer is not well understood. There is general agreement

[48] Upton, Speech to American Cancer Society Science Writers' Seminar, Mar. 25-28, 1979, at 2-3.

that chemical carcinogenesis involves changes in the genetic material of an individual cell, or small group of cells, or in the mechanisms by which cells regulate growth and differentiation. These changes cause the affected cells to grow without restraint, without performing the functions of normal cells, and eventually threatening the life of the host.[49]

These processes appear to be enormously complex. Some chemicals appear to accomplish these changes directly. Most seem to need to be "activated" by being metabolized by the body into the actually carcinogenic substances. Still other chemicals apparently "potentiate" or otherwise facilitate the action of others. Which chemicals operate in which of these manners is not always known.[50]

In addition, cancers usually appear to be the result of a sequence of steps: a series of changes caused in the same cells by repeated exposures to the same chemical, by a sequence of exposures to different substances, or a complex interaction of chemicals with genetic susceptibility, viruses or radiation. The theory of sequential steps suggests that cancer may be caused even by past exposure to a chemical long since eliminated from the body; that chemical may have been responsible for an early step in a process completed by other factors.[51]

[49] *See* BRAUN, THE BIOLOGY OF CANCER (1974); Weinstein, Yamaguchi, Gebert, & Kaighn, *Use of Epithelial Cell Cultures for Studies on the Mechanism of Transformation by Chemical Carcinogens*, 11 IN VITRO 130 (1975).

[50] *See* Weisburger, *Chemical Carcinogens*, in TOXICOLOGY 333 (Casarett & Doull eds. 1975) [hereinafter cited as Weisburger].

[51] Crump, Hoel, Langley & Peto, *Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2973 (1976) [hereinafter cited as Crump *et al.*].

The complexity of the processes by which a chemical gets from its point of entry (*e.g.*, lungs, skin, digestive system) to its point of damage adds further uncertainty. These absorption, distribution, and excretion processes are rarely more than partly known.[52] It also appears that there are certain chemical reactions that can "detoxify" some amounts of some carcinogens and perhaps certain biological mechanisms that can repair or destroy some damaged cells. These mechanisms do not appear to be fully effective, however.[53]

Moreover, the human population is genetically, geographically, and culturally heterogeneous. For this reason, it is thought that people vary in sensitivity to a particular carcinogen. It appears that genetic heterogeneity alone accounts for a substantial variation in human response. Subgroups exposed to other substances because of their diet, or place of residence or work, may be especially sensitive to particular substances.[54]

These apparent properties of chemically-induced cancer have led to a virtual consensus among expert scientists, committees, and institutions that "thresholds" for carcinogens—*i.e.*, doses for which no human cancer risk exists—cannot be determined.[55] While theoretically a threshold dose may exist for a given person exposed to a given substance in particular conditions, the enormous variation in sensitivities and in past and future exposures

[52] GOLDSTEIN, ARONOW, & KALMAN, PRINCIPLES OF DRUG ACTION: THE BASIS OF PHARMACOLOGY 129-226 (2d ed. 1974).

[53] *See id.* at 623-667. See also Weisburger, *supra* note 50.

[54] DRINKING WATER AND HEALTH, *supra* note 43, at 39; *see generally* articles in PERSONS AT HIGH RISK OF CANCER, *supra* note 10.

[55] *See e.g.*, SURGEON GENERAL'S REPORT, *supra* note 43; Schneiderman, Decoufle & Brown, *Thresholds for Environmental Cancer: Biological and Statistical Considerations*, —ANNALS OF THE N.Y. ACADEMY OF SCIENCES— (in press); DRINKING WATER AND HEALTH, *supra* note 43, at 37-48, NAS CHLORDANE/HEPTACHLOR EVALUATION, *supra* note 43.

to this and other substances is thought to preclude determining reliable thresholds for whole populations. For the same reasons, the size of the risk at particular doses may vary greatly for different people. Even if the size of the risk for a given person in given circumstances could be demonstrated, one would not necessarily know the size of the risk for members of a larger group.[56]

b. *Epidemiological Studies Are Capable of Identifying Carcinogens, But Not the Magnitude of Cancer Risks*

Epidemiological studies take advantage of the unfortunate fact that groups of people are already exposed to a wide variety of chemicals. The most fruitful studies are of occupational groups exposed to chemicals to which the general public is not exposed, or only at much lower levels. Studies of this type, for example, supplied the principal basis for identifying benzene as a cause of leukemia. The Infante study of workers in Ohio exposed to benzene in the manufacture of Pliofilm and numerous other studies discussed in the preamble to the benzene standard[57] demonstrate beyond doubt that benzene causes leukemia.

But epidemiological studies are relatively insensitive. Because of the small size of most occupational group studies, an effect generally will not be detected unless it is occurring in five to ten percent of the population. If the effect is relatively common, such as lung cancer, and has many chemical causes, an even greater response is needed from one chemical in order to be detected. For the most part, people are exposed to too many substances at unknown doses for unknown periods to permit the drawing

[56] DRINKING WATER AND HEALTH, *supra* note 43, at 39-47; Crump *et al.*, *supra* note 51.

[57] 43 Fed. Reg. 5918, 5925-32 (1978).

of statistically reliable conclusions from epidemiological studies about the magnitude of the risk.[58]

The same factors that render epidemiological studies insensitive as a means of identifying carcinogens make them extremely unreliable for quantifying the risks of the carcinogens they do identify.[59] Some of the most important factors are as follows.

First, sufficient latency periods often have not run to reveal the full effect. Latency in humans ranges from 15-40 years.[60] Second, dose information is often highly speculative, especially for periods of two or more decades ago, when exposure began. It is often difficult to determine even which workers in a factory were exposed, let alone at what level.[61] Third, not all exposed persons have been followed and their fate determined. Their illnesses and causes of death, or even whether they still live, is not determined. Since ill employees are the most likely to have left employ, the failure to follow them can seriously understate cancer incidence. Fourth, common cancers are often not related to their causes. Lung cancer, for example, appears to have many chemical causes. It is more difficult to relate this cancer to a specific chemical than one which is extremely rare and readily traced to a particular source.[62]

---

[58] *See* Hoover, *supra* note 41; ENVIRONMENTAL CANCER, *supra* note 41.

[59] *See* sources in note 58, *supra*.

[60] COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT 23 (1975).

[61] The benzene studies provide an example of this problem. See discussion at 43 Fed. Reg. 5927. Sometimes doses two or more decades past can be reconstructed only speculatively. For an effort to do such reconstruction, see Kramer & Mutchler, *The Correlation of Clinical and Environmental Measurements For Workers Exposed to Vinyl Chloride*, 33 AM. INDUS. HYGIENE ASS'N J. 19 (1972).

[62] *See* sources in note 58, *supra*.

c. *Animal Experiments Also Permit Identification of Carcinogens, But Not the Degree of Risk to Humans*

Lifetime studies on rodents are the major source of data on the carcinogenicity of chemicals. The animals' response to these chemicals is considered essentially similar to that of humans, so that a substance carcinogenic to one species is likely to be carcinogenic to the others. Nearly all of the chemicals whose human carcinogenicity has been proven epidemiologically have also been shown to cause cancer in animals. Most of the 65,000 chemicals in commerce pose no cancer risks. But there are at least several hundred chemicals that have been identified as carcinogens in animals, for which adequate epidemiological studies are unavailable.[63]

But animal studies cannot reliably indicate the magnitude of risks to people. To investigate directly the effects of the doses of carcinogen commonly experienced by people would require huge experiments. For example, to demonstrate with 95 percent confidence that a realistic dose of just one substance causes fewer than one cancer in a million subjects would require a test involving at least 6,000,000 animals. Such "mega-mouse" experiments would be impractically expensive.[64]

Scientists attempting to estimate the risks from commonly encountered doses use mathematical models of dose-response relationships to extrapolate from ex-

---

[63] Tomatis, Agthe, Bartsch, Huff, Montesand, Saracci, Walker & Wilburn, *Evaluation of the Carcinogencity of Chemicals: A Review of the Monograph Program of the International Agency for Research in Cancer*, 38 CANCER RESEARCH 877 (1978); Saffiotti, *Identifying and Defining Chemical Carcinogens*, in ORIGINS OF HUMAN CANCER, *supra* note 41, at 1311.

[64] Mantel & Schneiderman, *Estimating "Safe" Levels, a Hazardous Undertaking*, 35 CANCER RESEARCH 1379, 1383 (1975).

perimental results on animals at higher doses. However, reflecting the lack of knowledge of precisely what is happening at and above the cellular level, the different models yield widely divergent estimates of the risk associated with each low dose. While the major mathematical models all agree with observed results, they can differ by a factor of 100,000 on the size of the dose that creates a risk of one cancer in a million animals.[65]

Our ignorance of how to translate dose-response estimates across species lines adds more uncertainties to risk estimates. Not enough is known to determine confidently the relative sensitivity of humans and each species or strain of test animals. For example, people are bigger than animals; there is uncertainty whether the proper way to scale up doses is on the basis of relative body weights or on the basis of relative surface areas of tissue.[66] Moreover, in contrast to human genetic heterogeneity and diverse chemical exposures, test animals are inbred for genetic homogeneity in order to facilitate uniform, reproducible test results, and they are generally exposed to only one substance at a time. Consequently, there may be subgroups of the human population far more sensitive than these inbred strains, and there may be interactions between chemicals that the animal tests do not reveal.[67]

Recent attempts by a committee of the National Academy of Sciences to quantify the risks from saccharin graphically illustrate the uncertainties. Using the results of the recent animal studies, the various plausible models,

[65] Cornfield, *Carcinogenic Risk Assessment*, 198 SCIENCE 693, 694 (1977).

[66] Rall, *Problems of Low Doses of Carcinogens*, 64 J. WASH. ACAD. SCI. 63 (1974). See also NAS SACCHARIN STUDY, *supra* note 47, at 3-68 to 3-72 and table 3-8.

[67] *See* DRINKING WATER AND HEALTH, *supra* note 43, at 35; SCHNEIDERMAN, MANTEL & BROWN, *From Mouse to Man—Or How to Get From the Laboratory to Park Avenue and 53rd Street*, 246 ANNALS OF THE N.Y. ACADEMY OF SCIENCES 237 (1975).

and the differing assumptions about how to cross species line to humans, they attempted to quantify the effects of a consuming one can of diet soda per day. The results suggested that in each 50 million people there could be as few as 0.0007 cancers per year or as many as 3640. This is a range of error more than 5,000,000-fold.[68]

2. *Techniques for Quantifying Economic Impact*

Forecasting the costs of controlling or avoiding exposure to a carcinogen is also difficult. Adequate control of carcinogens sometimes requires significant changes in equipment and operating procedures. The precise cost of improved measures to control exposure is difficult to determine, and the uncertainty increases with the degree of change. Moreover, as costs increase, consumers of the dangerous chemical tend to use less of it. They shift to safer chemicals or to other means of accomplishing the purpose the dangerous chemical serves. The magnitude of these effects and their economic value are extremely difficult to predict. Over time consumers (whether industries or individuals) adjust and learn new ways of satisfying their needs with less of a dangerous chemical or with none at all. Thus the actual costs may turn out to be smaller than first predicted after some time for innovation and adjustment.[69]

Moreover, objective analysis of economic impacts is hampered by the fact that often the parties with the most accurate information on the costs and effects of controlling a carcinogen have little incentive to make it available.[70] The industries making and using benzene, for example, have the best access to technological and eco-

[68] NAS SACCHARIN STUDY, *supra* note 47, at 3-72, table 3-8.

[69] The uncertainties are illustrated by graphs in W. ROWE, AN ANATOMY OF RISK 233-34 (1977).

[70] See NATIONAL ACADEMY OF SCIENCES, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 51-58 (1977) [hereinafter cited as DECISION MAKING IN EPA]

nomic data to analyze the availability of substitutes and likely consumer responses, yet they may not feel that revealing it is in their commercial interest while a standard is under consideration.

An example illustrates the point. In 1974 the industries subject to the Secretary's standard for vinyl chloride stated that the one part per million standard for that carcinogen was technologically impossible to meet and that attempting to meet it would drive them into bankruptcy. The industries urged their positions without success before the Secretary, before the Second Circuit Court of Appeals,[71] and before this Court.[72] Yet within a month of the failure of their legal challenge, the companies began to announce dramatic technological advances and to drop their cost estimates to a fraction of their prior levels.[73] Polyvinyl chloride plastic today remains strongly competitive with other plastics despite compliance with the standard.[74]

3. *Comparing Health and Economic Interests*

There is no acceptable way of reducing health effects to dollars to allow comparison with the costs of controlling exposure. Economists have proposed a number of methodological approaches to such an evaluation.[75] But,

[71] *See* Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).

[72] *Id.*

[73] Greek, *Vinyl Chloride May Force Shortages by 1977*, CHEM. & ENGINEERING NEWS, Aug. 11, 1975, at 8, 9. *See also Goodrich Cuts Cost of Meeting VCM Limits*, CHEMICAL WEEK, Dec. 10, 1975, at 59.

[74] *PVC Rolls Out of Jeopardy, Into Jubilation*, CHEMICAL WEEK, Sept. 15, 1976, at 34.

[75] The various methods were surveyed and criticized by the Secretary in the preamble to his standard for coke oven emissions, 41 Fed. Reg. 46,750-51. For a concise summary of methods and problems, *see also* DECISION MAKING IN EPA, *supra* note 70, at 228-34.

none of the techniques can evaluate the questions of fairness which arise when the risks and benefits fall to different people, nor can they adequately evaluate the present value of preventing disease in the future.[76] In the end, they founder on the most basic ethical tenets, which turn away from consciously placing a monetary value on human life.

SUMMARY OF ARGUMENT

The Occupational Safety and Health Act empowers the Secretary of Labor to adopt highly protective standards in order to reduce the devastating toll of deaths, illnesses, and injuries in American workplaces. The Act places special emphasis on controlling exposure to chemicals that cause cancer and other fatal and disabling diseases among employees. Section 6(b)(5) of the Act directs the Secretary to set the standard for such a substance

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life.[77]

Congress recognized that with effects such as cancer, the hazards of chemicals in the workplace can be identified well before their precise magnitude can be known. Long latency periods, subtle cause-and-effect relation-

[76] *See generally* Baram, *Regulation of Health, Safety And Environmental Quality And The Use of Cost-Benefit Analysis*, Final Report to the Administrative Conference of the United States (1979); Fischhoff, *Cost-Benefit Analysis and the Art of Motorcycle Maintenance*, ~~43 Policy Analysis 64 (1977)~~ 8 Policy Sciences 177 (1977).

[77] 29 U.S.C. §655(b)(5).

ships, and complex interactions preclude having reliable *quantitative* data until long after the availability of reliable *qualitative* information. In the interim, because employees' lives and health are at stake, the Act permits—indeed requires—the Secretary to take action to prevent cancer, on the basis of such qualitative information, the best evidence then available.

By directing the Secretary to act on the basis of the best available evidence, the statute commits to him the determination of when, if ever, scientific knowledge has progressed sufficiently to allow reliable quantification. As long as he may reasonably determine such techniques are not yet reliable, the Act neither requires the Secretary to postpone taking protective action, nor demands that he undertake a sham quantitative analysis.

In this case, the Secretary has reasonably determined that quantitative risk assessment techniques do not reliably indicate the size of the cancer hazard. Accordingly, he concluded he must establish a standard for benzene, an undisputed carcinogen, using his best judgment about what is needed to protect employees, on the basis of the best qualitative evidence. He has not chosen to act blindfolded; rather, he has determined that quantitative risk assessment will not improve his vision.

Although the health of employees is the Secretary's paramount concern, Congress also recognized the need for practical considerations in setting standards. Consequently, the Act required the Secretary to set "feasible" standards. There is, however, nothing to support and much to refute the notion that the feasibility requirement, or any other provision of the Act, imposes on the Secretary the obligation to show through a quantitative analysis that the benefits of a standard outweigh its costs. Congress recognized the severe ethical and methodological limitations of such quantitative cost-benefit analysis. Not the least of these are the usual absence of reliable quantitative information about risks, and the absence of any acceptable way to place a dollar figure on the value of a life.

Despite the requirements and policies of the law, the lower court held that the Secretary may not adopt a standard to reduce the cancer hazard from benzene, unless he performs a quantitative assessment of the risk reduction to be gained, and provides a quantitative cost-benefit analysis demonstrating that these benefits bear a "reasonable relationship" to the costs to employers of complying with the standard.[78]

To reach its desired result, the court had to turn the terms and legislative history of the Occupational Safety and Health Act on their heads. Holding that "the best available evidence" and related phrases require quantitative risk assessment, the court imposed on them meanings exactly opposite to what their legislative history indicates.[79] Contrary to the court's conclusion, these phrases *require* preventive action while risks are still debated, rather than block it.

Recognizing it could find no support for quantitative cost-benefit in the term "feasible" or its legislative history, the court poured this meaning into an innocuous provision—"reasonably necessary" in the definition of standards—that Congress never contemplated would bear on the issue. The court also constructed a faulty parallel with the Consumer Product Safety Act.[80] The parallel would be of no help even if real, since the authors of the latter Act explicitly rejected quantitative cost-benefit analysis.

---

[78] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978).

[79] *Id.* at 504.

[80] *Id.* at 502-03.

In its zeal to require quantitative risk assessment and cost-benefit analysis, the court bent the statutory "substantial evidence" test for review into a barrier to achievement of the Act's protective policies. While the court allowed that the Secretary's decision was *rational*, it held that without a quantitative risk assessment this was not enough.[81] To so read the substantial evidence test would cancel the Secretary's authority—clearly indicated by the remainder of the Act—to act on the basis of qualitative evidence when he reasonably determines that it is the best available.

The Fifth Circuit's decision conflicts with all other cases reviewing the validity of standards promulgated under the Occupational Safety and Health Act, from the District of Columbia, Second, Third, and Eighth Circuits. It would prevent the Secretary from effectively fulfilling his statutory mandate to protect employees from chemically-induced cancer and other killing and disabling diseases. It would place requirements on the Secretary that Congress did not impose, and that the Secretary reasonably determined were inappropriate. For these reasons, the decision should be reversed.

ARGUMENT

I. THE OCCUPATIONAL SAFETY AND HEALTH ACT DOES NOT REQUIRE QUANTITATIVE JUSTIFICATION FOR STANDARDS TO PROTECT EMPLOYEES FROM CANCER-CAUSING CHEMICALS

The Occupational Safety and Health Act particularly emphasizes standards to protect employees from cancer and other killing and disabling diseases caused by toxic

[81] *Id.* at 503.

chemicals and dusts in the workplace. Section 6(b)(5) directs the Secretary to set the standard

> which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.[82]

Recognizing the long delays frequent between exposure to carcinogens and illness, the subtle nature of many cause-and-effect relationships, and the fact that employees' lives and health are at stake, Congress determined that a policy of minimizing exposure to these substances as much as feasible was the only one consistent with a prudent regard for public health. While obviously it would be desirable if more exact quantitative data were available on the risks of carcinogens and the costs of controlling them, the Occupational Safety and Health Act clearly reflects Congress' conclusion that the protection of public health from cancer-causing substances should not await the development of techniques needed to provide it. In effect, the Act represents a judgment that the potential human and economic costs to our nation of providing too little protection from this dread disease are too high to warrant awaiting more precise information, even though

[82] 29 U.S.C. §655(b)(5).

the standards the Secretary adopts may entail substantial expense, require technological innovation, or even cause significant economic change within an industry.

The lower court has proposed an entirely different approach from the precautionary one Congress adopted. It would prohibit the Secretary from adopting standards to protect employees from carcinogenic substances until he provided quantitative estimates of the reduction in risks associated with the proposed standard, and a quantitative analysis showing that the benefits outweighed the costs. This position, contrary to the understanding of all four of the other Courts of Appeal that have reviewed the validity of standards adopted under the Act, is as unwise a public health policy as it is contrary to the intention of the legislators who wrote the Act.

In attempting to justify its proclivity for quantification, the lower court could offer nothing more than a "*But see*" citation to the contrary decisions of the other circuits[83] and a lame assertion that the issues in those essentially identical cases were somehow different.[84] Similarly, it was forced to turn the Occupational Safety and Health Act inside out, disregarding the plain meaning and legislators' understanding of the terms Congress chose to address the proper manner of evaluating health evidence and the role of economic factors in standard-setting, while pouring its own notions of the role of costs and risk assessment into terms not meant to contain them.

At some point in the future, techniques for quantifying the magnitude of risks from workplace carcinogens and comparing the costs and benefits of alternative standards may be developed which are capable of increas-

[83] American Petroleum Inst. v. OSHA, 581 F.2d 493, 504 (5th Cir. 1978).

[84] *Id.* at 505.

ing the precision of occupational safety and health standards. But to this point Congress has not been persuaded, and the lower court has no power to substitute its own conclusions for those of the legislature.

A. Conditioning Standards on Quantitative Assessments of Risk Conflicts with the Congress' Desire to Prevent Disease Before It Develops.

Since cancer is a disease that resists a cure, preventing it is one of the most basic purposes of the Occupational Safety and Health Act. Thus the Act empowers—indeed requires—the Secretary to prevent exposure to carcinogens before they take their toll in human life. Since cancer is a disease that develops only after a long latency period and one whose mechanisms are not precisely known, prevention necessarily requires acting before all the data are available to assess precisely the magnitude of the risk. All too often, definite proof that a substance causes cancer, let alone evidence to assess the magnitude of its potency, can be found only after unacceptable damage to public health has already occurred—after some people have already contracted killing or disabling disease and many more have been irreversibly exposed.

It is abundantly clear in the Congressional debates accompanying the passage of the Occupational Safety and Health Act that Congress understood the import of these considerations and intended that action should occur without waiting until the numerical toll could be assessed.

1. The Primacy of the Goal of Preventing Occupationally-Caused Disease

The legislators who wrote the Occupational Safety and Health Act repeatedly stressed the seriousness of the problem of occupationally-induced disease, and their conclusion that rapid preventive action was both required and practical. Section 6(b)(5) reflects this urgency

throughout, requiring that each standard "most adequately assure[ ]," to the degree feasible, "that no employee will suffer material impairment of health or functional capacity," even after life-long exposure.[85] It requires the Secretary to seek "the highest degree of health and safety protection for the employee."[86]

Moreover, the statute directs the Secretary to act on "the best available evidence" and "the latest available scientific data in the field."[87] By these phrases, the House Report said, the legislators intended the Secretary to take preventive action promptly without waiting until the evidence necessary to determine the precise magnitude of the threat eventually becomes available: "The Committee feels it is vital that when the Secretary sets an occupational health standard he does so on the basis of the best available professional evidence; *it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinions.*"[88] By contrast, not a single Senator or Representative even suggested an intent to require quantitative assessment of the risks before the Secretary acted.

The legislative history of the Act shows that Congress clearly recognized the killing and disabling properties of a growing number of chemicals and dusts once thought to be safe, and the problems of latency and statistical subtlety that impede early discovery of the magnitude of risks.[89] These factors added urgency to taking protective,

[85] 29 U.S.C. §655(b)(5).

[86] *Id.* The references to "employee" in the singular emphasize the goal of protecting all employees, even those more sensitive than average. *See* HOUSE REPORT, *supra* note 15 at 18.

[87] 29 U.S.C. §655(b)(5).

[88] HOUSE REPORT, *supra* note 15, at 18 (emphasis added).

[89] *See e.g.*, Statement of Senator Saxbe, *reprinted in* SUBCOMM. ON LABOR OF THE SENATE COMM. ON LABOR AND PUBLIC WELFARE, LEGISLATIVE HISTORY OF THE OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970 338-39 (1971) [hereinafter cited as LEG. HIST.].

preventive action as soon as a substance's dangers are identified, without waiting for years until the precise contours of the danger are fully researched.

The Senate Report on the bill emphasized the growing pattern of discovering life-threatening dangers even in familiar substances, as well as in the new chemicals of the post World War II period:

> [M]aterials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. Carcinogenic chemicals, lasers, ultrasonic energy, beryllium metal, epoxy resins, pesticides, among others, all present incipient threats to the health of workers. Indeed, new materials and processes are being introduced into industry at a much faster rate than the present meager resources of occupational health can keep up with. It is estimated that every 20 minutes a new and potentially toxic chemical is introduced into industry. New processes and new sources of energy present occupational health problems of unprecedented complexity.[90]

The Report took especially seriously the developing edge of scientific knowledge on occupationally-induced disease:

> Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be

[90] SENATE REPORT, *supra* note 1, at 2.

> direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.[91]

In addition, the Report observed that "the modern worker encounters health hazards involving complex, often synergistic interactions of numerous physical and chemical agents. . . ."[92]

The Committee cited the need to set standards forthwith to protect employees from the chemicals, metals, and dusts named above, as well as "ancient" poisons such as lead and mercury. The Committee did not consider quantification of the risk a precondition to regulation; employee protection from identified killers should not be postponed solely because their precise potency was uncertain.[93]

The House Report reiterated the same themes. It cited the dangers of these same chemicals and the rapidly growing knowledge of new dangers.[94] Moreover, the Committee stated:

> [W]orkers are in daily contact with literally hundreds of new chemicals and formulations about which little is known. As occupational health research becomes more sophisticated, there is every indication that the toxicity of the fumes, gases, and chemicals to which workers are exposed will be discovered by researchers.[95]

---

[91] *Id.*
[92] *Id.* at 19.
[93] *Id.* at 2-4.
[94] HOUSE REPORT, *supra* note 15, at 14-15.
[95] *Id.* at 19.

As stated above, the House Committee emphasized that in setting standards for toxic substances, the Secretary must not be "paralyzed" by scientific uncertainties and differences of opinion.[96] He must resolve the uncertainties in favor of protecting the employees.

2. *Judicial Recognition of the Primacy of Preventing Disease*

Except for the Fifth Circuit, the Courts of Appeals that have reviewed OSHA standards for carcinogens have all correctly emphasized the law's requirement to take a precautionary, preventive view of the evidence of health harm. They have repeatedly upheld the Secretary's authority to set standards on the basis of qualitative evidence that identifies a substance as a carcinogen. Only the Fifth Circuit has sought to make quantifying the magnitude of risk a necessary prerequisite to protective action.

In *Industrial Union Dep't, AFL-CIO* v. *Hodgson*,[97] the District of Columbia Circuit upheld the standard for asbestos. The Secretary's knowledge of the effects of asbestos precisely paralleled his knowledge about benzene in the case under review here: he had firm evidence that asbestos was a carcinogen, although the precise effects of particular doses was not known. The court observed that the statute required the Secretary to base standards upon conclusions drawn from well-established data and from information "on the frontiers of scientific knowledge."[98] The court concluded:

> [I]n this case the evidence indicated that *reliable data is not currently available with respect to the precisely predictable health effects of various levels of exposure to asbestos dust; nevertheless, the Sec-*

---

[96] *Id.* at 18.
[97] 499 F.2d 467 (D.C. Cir. 1974).
[98] *Id.* at 474.

> *retary was obligated to establish some specific level as the maximum permissible exposure.* After considering all the conflicting evidence, the Secretary explained his decision to adopt, over strong employer objection, a relatively low limit in terms of the severe health consequences which could result from over-exposure. *Inasmuch as the protection of the health of employees is the overriding concern of* [*the Act*], *this choice is doubtless sound. . . .*[99]

The Second Circuit faced the identical issue reviewing the standard for vinyl chloride. This chemical had been shown to cause cancer in workers exposed to relatively high doses (around 200 parts per million) and in animals at lower doses (down to 50 ppm). In *Society of the Plastics Industry* v. *OSHA*,[100] the court rejected the claim that the Secretary could not reduce exposures to one ppm without evidence of human harm down to that level. The court acknowledged that "though the factual finger points, it does not conclude."[101] Nonetheless, "Under the command of [the Act], it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient."[102]

The Third Circuit upheld the Secretary's standard for ethyleneimine, another carcinogen, in *Synthetic Organic Chemical Manufacturers Ass'n* v. *Brennan*,[103] on the basis of two animal studies and the judgment of committees of cancer experts that current knowledge showed no level of exposure to a carcinogen can be considered completely safe.[104] The court found no requirement that the Secretary be able

[99] *Id.* at 475 (emphasis added).

[100] 509 F.2d 1301 (2d Cir. 1975), *cert. denied*, 421 U.S. 992 (1975).

[101] *Id.* at 1308.

[102] *Id.*

[103] 503 F.2d 1155 (3rd Cir. 1974).

[104] *Id.* at 1157-61.

to quantify the risk. And in *American Iron & Steel Institute* v. *OSHA*,[105] the court held that the Secretary had ample evidence, from epidemiological studies of coke oven workers and expert opinion on the issue of safe doses for carcinogens, to conclude that coke oven emissions were carcinogenic and no level of exposure could be considered risk-free.[106]

The lower court decision is starkly inconsistent with those of its sister circuits. These courts have correctly perceived that statutory phrases such as "the best available evidence"[107] permit—even require—the Secretary to take protective action when he discovers that a substance is a carcinogen, without waiting for the development of the capability to quantify the magnitude of the threat to life. Yet the Fifth Circuit turned these phrases on their heads, interpreting them to *block* preventive action.[108] This reading ignores their plain meaning and the legislative history indicating that the very purpose of such

[105] 577 F.2d 825 (3rd Cir. 1978).

[106] *Id.* at 831-32.

[107] Occ. Safety & Health Act § 6(b), 29 U.S.C. §655(b)(5).

[108] American Petroleum Inst. v. OSHA, 581 F.2d 493, 504 (5th Cir. 1978). Besides "the best available evidence" and "the latest scientific data in the field," the court pointed to two other phrases in section 6(b)(5): "research, demonstrations, experiments, and such other information as may be appropriate," and "experience gained under other health and safety laws." If the last phrase indicates anything at all, it cuts against the lower court, for the weight of experience under other laws upholds the validity of the Secretary's approach to carcinogen regulation. *See e.g.*, Environmental Defense Fund v. EPA, — F.2d —, 8 ELR 20765 (D.C. Cir. 1978) (toxic water pollutants); Certified Color Mfrs. Ass'n v. Mathews, 543 F.2d 284 (D.C. Cir. 1976) (food color additives); Environmental Defense Fund v. EPA, 510 F.2d 1291 (D.C. Cir. 1975) (pesticides). As for "research . . . and such other information as may be appropriate," this phrase most fairly read envisions the use of just such epidemiological studies as the ones on which the Secretary relied.

phrases was to permit the Secretary to act to protect employees from known dangers without being "paralyzed" by the lack of scientific certainty on the extent of the hazard.[109] Yet rather than address the inconsistency of its position with the law and the other circuits, the court lamely refused even to discuss the contrary cases.[110]

In sum, the Act and the legislative history empower the Secretary not only to find facts about chemicals' toxicity, but also to make judgments where necessary to resolve scientific unknowns. The power to make such judgments is a necessary consequence of the Act's mandate that the Secretary set standards for chemicals identified as carcinogens. To be sure, the Secretary cannot regulate every existing substance simply because it might be harmful; he must have a firm basis for identifying a substance as dangerous, such as epidemiological or animal studies. But where *qualitative* identification of risk is best that can be done, Congress did not pose an impossible barrier to regulation.

Shortly after the decision in this case, the District of Columbia Circuit upheld toxic water pollutant standards for polychlorinated biphenyls (PCBs), which have produced cancer in laboratory animals. The court stated that when faced with claims of substantial economic impact,

> the temptation to demand that the agency furnish conclusive proof of carcinogenicity as support for the regulations is great. However, the decision to delegate authority to an agency to control suspected carcinogens is a legislative judgment that is not open to question in this court. Congress' direction to EPA to protect against incompletely understood dangers could not be carried out if we were to adopt the proof requirements advocated by industry petitioners.

[109] HOUSE REPORT, *supra* note 15, at 18.

[110] American Petroleum Inst. v. OSHA, 581 F.2d 493, 505 (5th Cir. 1978).

> What scientists know about the causes of cancer is how limited is their knowledge. The record in this case demonstrates that it may take decades for human exposure to carcinogens to result in cancer; in the meantime, the case for inferring a cancer danger with respect to an incompletely understood substance is vigorously disputed. If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result.[111]

The Fifth Circuit has succumbed to this temptation and substituted its judgment for that of Congress.

B. The Requirement that Standards be Feasible Does Not Mandate a Quantitative Demonstration that their Benefits Exceed Their Costs.

While the purpose of the Occupational Safety and Health Act was to decrease drastically the incidence of workplace-induced disease, its authors recognized that practicality imposed limits on the achievement of this goal. Thus in section 6(b)(5) they limited the measures that the Secretary might require to reduce exposure to cancer-causing substances to those that were "feasible." While the use of the term feasibility obviously implies that the Secretary must consider the economic cost of proposed regulations to employers when he adopts workplace exposure standards for carcinogens, the legislative history demonstrated that Congress did not intend the consideration of economic costs to impede vigorous action to prevent occupationally-induced disease. In short, while recognizing that a wholly risk-free working environment might not always be practical, the legislators did not

[111] Environmental Defense Fund v. EPA, —F.2d—, —, 8 ELR 20765, 20780 (D.C. Cir. 1978).

contemplate an unrealistic quantitative demonstration that the benefits of a proposed standard outweighed its costs to industry.

1. ***The Legislative History Of The Term "Feasible" Shows That Congress Intended Only A Limited Role For Cost Considerations In Setting Standards***

Section 6(b)(5) directs the Secretary to set standards that prevent impairment of employees' health "to the extent feasible."[112] The legislative history shows that all congressional discussion of the role of economic considerations in setting standards was structured around this feasibility requirement. Nothing in this provision or its legislative history can be construed as requiring quantitative cost-benefit analysis.

Tracing the meaning of the feasibility requirement begins with the bill reported by the House Committee in July 1970.[113] This bill, the so-called Daniels bill, would have established the employees' right to standards providing fully safe workplaces without any qualification:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately assures, on the basis of the best available professional evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy, even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[114]

The Senate Committee, which reported a bill several months later, added the feasibility requirement to the

[112] 29 U.S.C. §655(b)(5).

[113] H.R. 16785, *reprinted in* HOUSE REPORT, *supra* note 15, at 1-14.

[114] *Id.* §7(a)(4).

Daniels formulation. As reported, Section 6(b)(5) attained its nearly final form:

> The Secretary, in promulgating standards under this subsection, shall set the standard which most adequately *and feasibly* assures, on the basis of the best available evidence, that no employee will suffer any impairment of health or functional capacity, or diminished life expectancy even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of such standards shall be based on research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, *the feasibility of the standards*, and experience gained under this and other health and safety laws.[115]

The feasibility requirement was added in committee at the suggestion of Senator Javits, one of the principal architects and managers of the bill. He explained the amendment in his individual views attached to the Report:

> As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement in the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all.[116]

[115] S. 2193 §6 (b)(5) (Oct. 5, 1970), *reprinted in* LEG. HIST., *supra* note 89, at 242 (emphasis added).

[116] SENATE REPORT, *supra* note 1, at 58.

The Senate Report reiterated that "standards promulgated under section 6(b) shall represent feasible requirements. . . ."[117]

The comments of Senator Javits in the Committee Report,[118] and a colloquy on the Floor between Senators Williams and Dominick over the final fine-tuning amendment to section 6(b)(5),[119] show that Congress recognized completely risk-free workplaces might not always be possible to achieve. The feasibility limit was intended to free the Secretary from the duty to set absolutely safe standards in those situations. Congress also recognized that it would not make sense to protect employees by eliminating their jobs in a wholesale manner. But these legislators' statements, and many others in the Senate and House Reports and floor debates, also underscore that the standards must drastically reduce the intolerably high rates of work-related deaths, illnesses, and injuries.[120] Congress recognized that sometimes adequate protection

[117] *Id.* at 7.

[118] *Id.* at 58.

[119] Amendment No. 1058, *reprinted in* LEG. HIST., *supra* note 89, at 502-03 (colloquy between Senators Williams and Dominick). In his original remarks on this subject, Senator Dominick missed the point of Senator Javits' feasibility amendment in committee, which was to relieve the Secretary of the obligation to set standards guaranteeing complete safety in all cases. *Id.* at 480-82 (remarks of Senator Dominick.) But after changing the Committee's "most adequately and feasibly assures" to the final version's "most adequately assures, to the extent feasible," (thereby expressing feasibility syntactically as a limitation but not changing meaning), Senators Dominick, Javits, and Williams came to full accord. *Id.* at 502-03.

[120] *See e.g.*, SENATE REPORT, *supra* note 1, 2-4; HOUSE REPORT, *supra* note 15, at 14-16. *See also*, LEG. HIST., *supra* note 89, at 411-14 (remarks of Sen. Williams), 509-11 (remarks of Sen. Yarborough), 512-13 (remarks of Sen. Muskie), 518 (remarks of Sen. Nelson), 522 (remarks of Sen. Cranston), 985 (remarks of Rep. Perkins), 1212 (remarks of Rep. Daniels).

would entail substantial expense and sometimes would even result in closing some businesses.[121] As Senator Eagleton stated, the costs of assuring such protection must be borne as "necessary costs of doing business." He added: "[W]e can no longer permit profits to be dependent upon an unsafe or unhealthy worksite."[122]

The legislative history contains not a single statement by any member of the House or Senate suggesting that decisions should be reached through quantitative cost-benefit analysis. Indeed, the legislative history reveals a strong hostility to this approach, particularly to the idea of putting a dollar price on human life. As Senator Yarborough, then chairman of the full committee that reported the bill, stated: "We are talking about people's lives, not the indifference of some cost accountants."[123]

2. *Prior Cases Have Concluded That Costs Are To Be Accorded a Limited Role in Setting Standards*

The cases reviewing standards prior to *American Petroleum Institute* were unanimous that the requirement that standards be feasible is the limit of economic concern in the Act. The District of Columbia, Second, and Third Circuits all upheld the Secretary's "lowest feasible level" approach to setting standards for carcinogens. In addition, the Third and Eighth Circuits specifically rejected claims that the Act requires quantitative cost-benefit analysis.

[121] Both the Senate and House Committees contemplated that some substances were simply too dangerous to remain in use. *See* discussion of betanapthylamine, a very potent carcinogen, SENATE REPORT, *supra* note 1, at 4; HOUSE REPORT, *supra* note 15, at 15. *See also* the statement by Senator Saxbe: "It is a real question to me as to whether asbestos can be used at all, whether it can be handled," *reprinted in* LEG. HIST., *supra* note 89, at 338.

[122] LEG. HIST. at 1150-51 (remarks of Sen. Eagleton).

[123] *Id.* at 510 (remarks of Sen. Yarborough).

In *Industrial Union Dep't, AFL-CIO* v. *Hodgson*,[124] reviewing the asbestos standard, the District of Columbia Circuit stated: "There can be no question that [the Act] represents a decision to require safeguards for the health of employees even if such measures substantially increase production costs."[125] The court recognized that feasibility imposed a practical limit on standards. Citing Senator Javits' comments in the Committee Report, the court stated:

> The thrust of these remarks would seem to be that practical considerations can temper protective requirements. Congress does not appear to have intended to protect employees by putting their employers out of business—either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible.[126]

On the other hand, short of this drastic result the costs of employee protection must be borne. When lives are at stake, standards cannot be restricted to the lowest common denominator that the most recalcitrant employer will [redacted] accept:

> Standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely. Nor does the concept of economic feasibility necessarily guarantee the continued existence of individual employers. It would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the

[124] 499 F.2d 467 (D.C. Cir. 1974).
[125] *Id.* at 477.
[126] *Id.* at 477-78.

> industry and is consequently financially unable to comply with new standards as quickly as other employers.[127]

The court opined that extreme burdensomeness might be reason for phasing requirements in over some lead time.[128] But it did not suggest even extremely burdensome standards could never be imposed. Moreover, the court emphasized that the Act did not permit the Secretary to delay standards "needlessly."[129]

In *Society of the Plastics Industry* v. *OSHA*,[130] reviewing the standard for another carcinogen, vinyl chloride, the Second Circuit, Justice Clark writing, articulated the technology-forcing character of the Act:

> In the area of safety, we wish to emphasize, the Secretary is not restricted by the status quo. He may raise standards which require the development of new technology, and he is not limited to issuing standards based solely on devices already fully developed.[131]

In *AFL-CIO* v. *Brennan*,[132] the Third Circuit agreed that standards may require technological innovation and may alter the economic status quo. The court stated that although standards must be feasible,

> we agree with the Second Circuit in *Society of Plastics* . . . that, at least to a limited extent, [the Act] is to be viewed as a technology-forcing piece of legislation. Thus the Secretary would

[127] *Id.* at 478 (footnote omitted).
[128] *Id.*
[129] *Id.* at 479.
[130] 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).
[131] *Id.* at 1309.
[132] 530 F.2d 109 (3rd Cir. 1975).

> not be justified in dismissing an alternative to a proposed health and safety standard as infeasible when the necessary technology looms on today's horizon.[133]

The Third Circuit also held that imposing substantial costs on industry was contemplated within the notion of feasibility. It held that standards need not be limited to the lowest common denominator that all employers in an industry will accept: "Congress did contemplate that the Secretary's rulemaking would put out of business some businesses so marginally efficient or productive as to be unable to follow standards otherwise universally feasible."[134] Moreover, the court suggested that some work was too dangerous to be permitted, especially if economic consequences of doing without such activities were relatively mild:

> We do not question that there are industrial activities involving hazards so great and of such little social utility that the Secretary would be justified in concluding that their total prohibition is proper if there is no technologically feasible method of eliminating the operational hazard.[135]

In *American Iron and Steel Institute* v. *OSHA*,[136] the Third Circuit reiterated this approach, upholding the feasibility of the standard to control carcinogenic coke oven emissions. The court held that the Act permitted the Secretary to base the standard on the performance of the best plant in operation and on improvements that could be reasonably forecast in its performances, by using additional technology in use elsewhere or "looming on today's

[133] *Id.* at 121 (citation and footnote omitted).
[134] *Id.* at 123 (footnote omitted).
[135] *Id.* at 121.
[136] 577 F.2d 825 (3rd Cir. 1978).

horizon."[137] The court upheld the Secretary's conclusion that the cancer hazard warranted the cost of the standard, which the employers admitted they could bear without significant disruption.[138] Moreover, the court approved the Secretary's rejection of quantitative cost-benefit analysis.[139]

The Eighth Circuit also explicitly rejected quantitative cost-benefit analysis in *Arkansas-Best Freight Systems* v. *Occ. Safety & Health Rev. Comm'n.*[140] The court quoted with approval the discussion of feasibility in *Industrial Union Dep't* and added: "The Act does not attempt to balance as neatly as does Arkansas-Best the costs of compliance against the cost of employees' injuries."[141] The court held that the standard there in question was within the Secretary's legislative grant of power "to protect the health of employees even though increased production costs may result."[142]

These four courts found nothing in the statute's notion of feasibility or any other provision of the Act to require quantitative risk assessment or cost-benefit analysis. In this regard they stand in stark contrast to the decision here under review. In this case the Fifth Circuit did not even dispute the other courts' understanding of the notion of feasibility. Recognizing the hopelessness of finding support for its quantitative requirements in this term, the court merely brushed it away. In an act of pure judicial legislation the court poured its quantitative requirements into the unwilling vessel of the phrase "reasonably necessary" in section 3(8). But this provision offers the court no support either.

[137] *Id.* at 833-35.
[138] *Id.* at 836-37.
[139] *Id.* at 836.
[140] 529 F.2d 649 (8th Cir. 1976).
[141] *Id.* at 654.
[142] *Id.* at 653.

C. The Lower Court Erred In Holding That Quantitative Cost-Benefit Analysis Is Mandated by the Requirement that Standards Be "Reasonably Necessary."

Section 3(8)[143] supplies no additional requirements regarding the role of economic considerations in setting standards. Instead, it merely means that the measures the Secretary includes in a standard must be rationally connected to alleviating the hazard at which the standard is aimed.

1. *The Legislative History Shows That "Reasonably Necessary" Has No Bearing On The Role Of Cost Considerations*

In contrast to the extensive legislative history on the feasibility requirement, section 3(8) received absolutely no discussion. It was an innocuous, uncontroversial provision common to every bill introduced on occupational safety and health in the 91st Congress.[144] Some of these bills differed substantially on the role of economic considerations. Yet all bills defined standards the same way. Thus the legislators could not have understood this provision to bear at all on this issue, let alone to create a quantitative cost-benefit analysis requirement.

The comments of Senator Javits, one of the legislators most concerned to assure that the Secretary would consider economic aspects of standards, make this clear. Despite the fact that all bills contained the "reasonably necessary" provision, Javits stated that without the feasibility amendment the Daniels bill "might be interpreted to require absolute health and safety in all cases," and the

[143] 29 U.S.C. §652(8).

[144] Each bill introduced into the 91st Congress defined occupational safety and health standards as requirements either "reasonably necessary" or "reasonably necessary or appropriate" to provide safe or healthful employment and places of employment. *See* the bills collected in LEG. HIST., *supra* note 89.

Administration bill would "contain[ ] no criteria for standards at all."[145] If he had attached *any* importance to section 3(8), Javits could not have reached this conclusion.

2. *"Reasonably Necessary" Merely Requires A Rational Connection Between The Means And Objectives of Standards*

Section 3(8) has a far more natural meaning than the lower court wished to force upon it. By defining standards as measures "reasonably necessary or appropriate" to provide safe or healthful workplaces, this provision merely requires the Secretary to show that measures have a rational connection to reducing the hazard at which the standard is aimed. Thus, it prohibits the Secretary from imposing patently unnecessary or irrelevant requirements, such as fire-fighting equipment for dealing with a non-flammable substance. There can be no serious contention that this lenient test of relevance requires the Secretary to quantify cancer risk. This conclusion would negate the precautionary approach so clearly indicated by the remainder of the statute and its legislative history.

D. The Consumer Product Safety Act Does Not Support The Lower Court's Construction Of The Occupational Safety and Health Act.

Unable to find any support for quantitative cost-benefit analysis in the Occupational Safety and Health Act or its legislative history, the court turned to a completely independent statute adopted two years later. The court asserted that section 3(8) is identical to certain provisions in the Consumer Product Safety Act,[146] which the court further asserted require quantitative cost-benefit analysis. Neither assertion is correct.

[145] SENATE REPORT, *supra* note 1, at 58.

[146] 15 U.S.C. §§2051-2081.

1. *The Two Acts Are Not Parallel*

Section 3(8) of the Occupational Safety And Health Act defines standards as measures "reasonable necessary or appropriate to provide safe or healthful employment."[147] Sections 7(a) and 9(c)(2)(A) of the Consumer Product Safety Act (CPSA) limit standards under that Act to requirements "reasonably necessary to eliminate or reduce an unreasonable risk of injury".[148] Comparing these provisions, the court stated: "We decline to construe the precisely similar requirements of these two Acts differently or to read words out of the OSHA legislation."[149] In fact, the provisions are not "precisely similar," and the court has read words *into* the Occupational Safety and Health Act.

The court failed to comprehend that "unreasonable risk," not "reasonably necessary," is the phrase which establishes the obligation to consider costs in the CPSA. This is clearly evident in the CPSA legislative history.[150] The phrase "unreasonable risk" is pointedly absent from the Occupational Safety and Health Act. So rather than read "reasonably necessary" *out* of the Act, the court has read "unreasonable risk" *in*.

2. *The Consumer Product Safety Act Does Not Require Quantitative Cost Benefit Analysis*

Even if the CPSA were parallel to the Occupational Safety and Health Act, it would provide the lower court no support, because the CPSA does not require quantitative cost-benefit analysis. The House Report on this statute specifically rejected cost-benefit analysis as an element of

[147] 29 U.S.C. §652(8).

[148] 15 U.S.C. §§2056(a), 2058(c)(2)(A).

[149] American Petroleum Inst. v. OSHA, 581 F.2d 493, 502 (5th Cir. 1978).

[150] *See* H.R. REP. NO. 1153, 92d Cong., 2d Sess. 33 (1972) (House Report on Consumer Product Safety Act).

determining "unreasonable risk." The committee made clear that the Commission must consider the traditional elements of the tort law reasonableness test: the probability and gravity of harm and the effect of regulation on the product's utility, cost, or availability.[151] The committee then added the following explicit caveat: "There should be no implication, however, that in arriving at its determination the Commission would be required to conduct and complete a cost-benefit analysis prior to promulgating standards under this Act."[152] Thus, even in enacting "unreasonable risk" statutes Congress recognizes that formal, quantitative techniques are not adequate to the decision-making task.

The rejection of quantitative cost-benefit analysis for determining "unreasonable risk" is by no means an anomaly of the CPSA. For example, Congress reached the same conclusion in enacting the Toxic Substances Control Act[153] in 1976. The House Report stated:

> During the hearings a number of witnesses recommended that the bill include a definition of unreasonable risk. Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors *which cannot be defined in precise terms and is not a factual determination but requires an exercise of judgment on the part of the person making it*, the Committee did not attempt a definition of such risk. In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of pro-

[151] *Id.*

[152] *Id.*

[153] 15 U.S.C. §§2601-2629.

posed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes . . . and other adverse effects which such proposed action may have on society.

The balancing process described above *does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with the substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.*[154]

The fact that these "unreasonable risk" statutes explicitly reject quantitative cost-benefit analysis makes the lower court's attempt to use them to shoehorn quantitative analysis into the Occupational Safety and Health Act even less plausible.

II. THE SECRETARY ACTED WELL WITHIN HIS DELEGATED AUTHORITY IN DECLINING TO ADOPT QUANTITATIVE RISK ASSESSMENT

The Occupational Safety and Health Act establishes the basic criteria for standards for toxic substances: the

[154] H.R. REP. NO. 1341, 94th Cong., 2d Sess. 13-14 (1976) (footnote omitted, emphasis added), The footnote quoted from an influential study on chemical regulation and decision making:

> *Highly formalized methods of benefit-cost analysis can seldom be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority.*

NATIONAL ACADEMY OF SCIENCES, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 44 (1975) (emphasis in original).

goal of no impairment of health, the duty to take preventive action on the basis of the best available evidence, and the constraint of feasibility.[155] But within the bounds of these criteria, the Act delegates to the Secretary substantial responsibilities to determine which substances shall be covered by standards and what requirements such standards shall contain.

In this case, the Secretary determined from repeated epidemiological studies that benzene causes leukemia in humans. He also concluded that there was very little margin, if any at all, between the benzene levels at which the chemical had already been shown to induce leukemia in humans and the existing 10 parts per million (ppm) standard, which had been developed years before and was aimed only at benzene's non-malignant effects.

Relying on the best expertise among cancer scientists, the Secretary determined that a safe level of human exposure to a carcinogen cannot be demonstrated, and that the size of the cancer risk at particular doses cannot now be established with any useful precision. He concluded, however, that a 90 percent reduction in exposure would significantly reduce employees' risks, and that such a reduction was feasible. Consequently, he set the new standard at one ppm.

The Secretary's decision was well within the statutory criteria that bound his delegated authority. His determinations were supported by both the best available scientific evidence and expertise. The basis for each of his judgments was well represented in the record of the decision.

In cases with essentially identical issues and records, the three other Courts of Appeals to review the Secretary's carcinogen standards have respected the Secre-

[155] Occ. Safety & Health Act § 6(b)(5); 29 U.S.C. § 655(b)(5).

tary's expertise and his mandate and upheld his decisions.[156] On the issue of quantifying risk, they have respected his expert judgment that the quantitative techniques are not sufficiently precise or reliable to be useful in determining standards. In fact, these courts have recognized that the Secretary would exceed his authority if he delayed acting until cancer risks could be reliably quantified, since the statute mandates standards to protect employees from life-threatening hazards on the basis of qualitative evidence when that is the best available.

The lower court in this case, however, held that unless the Secretary showed quantitatively the amount by which the new benzene standard would reduce the employees' cancer hazard, his decision could not be supported by substantial evidence.[157] With this holding, the lower court simply substituted its judgment for the Secretary's on the question whether benzene's cancer risk at particular doses can be reliably quantified. But the decision whether these techniques are sufficiently reliable that they constitute an appropriate basis for determining permissible exposure levels to carcinogens is a judgment committed to the Secretary, to which, if adequately supported and rational, the courts must defer. The lower court's drastic overestimation of the accuracy and reliability of the techniques for quantifying risk classicly illustrates the dangers of appellate judges' venturing into areas requiring detailed knowledge of a highly complex body of scientific study and thought.

---

[156] Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); Society of the Plastics Industry v. OSHA, 509 F.2d 1301 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975); Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155 (3rd Cir. 1974); American Iron & Steel Inst. v. OSHA, 577 F.2d 825 (3rd Cir. 1978).

[157] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503 (5th Cir. 1978).

A. The Substantial Evidence Test Does Not Permit The Court To Substitute Its Judgment For The Secretary's On The Reliability Of Quantitative Risk Assessments

1. *Standard Setting Under The Occupational Safety And Health Act Involves A Mixture Of Fact-Finding And Policy-Making*

The Secretary's determination in setting standards for carcinogens under section 6(b)(5) consist of both fact-finding and policy-making. He begins with a core of well-established facts about a chemical's toxicity. In this instance, epidemiological studies establish firmly that benzene causes leukemia. But his inquiry does not end with traditional fact-finding, because the solid facts do not supply the complete picture. The Act mandates that the Secretary take preventive action on the best available evidence.[158] This means that he must take into [redacted] consideration the qualitative but not completely precise evidence of harm, and, relying on the best scientific expertise, resolve the uncertainties as to the magnitude of the cancer risk in the manner that most protects employees' health.

These determinations to resolve scientific uncertainties are essentially policy judgments. The power to make these policy judgments is a necessary consequence of the Act's mandate to protect employees from identified hazards on the basis of the best available evidence. Restricted to traditional fact-finding, the Secretary would only be able to protect workers from the doses of carcinogens that already have been shown to kill, despite the strong but not completely certain belief that lower doses are dangerous too. The Secretary necessarily must have the most discretion to make such protective policy judg-

---

[158] Occ. Safety & Health Act § 6(b)(5), 29 U.S.C. § 655(b)(5).

ments with regard to the most serious health effects, such as cancer, and in situations where difficulties in precisely pinning down the risks are greatest.[159]

The determinations that safe doses of carcinogens cannot be identified, that lower doses are safer than higher ones, and that risks cannot be reliably quantified are mixed conclusions of fact and policy. They have a firm base in observed facts, supplemented by scientific theory of the processes of cancer. Ultimately, however, they rest on the judgments guided by the policy of the Act to resolve doubts about safety in the employees' behalf.

2. *The Substantial Evidence Test Does Not Prohibit The Secretary From Making Policy Judgments*

The Occupational Safety and Health Act provides for basically informal rulemaking of the kind traditionally associated with policy-setting. Section 6(b) provides for notice-and-comment procedures, supplemented with an opportunity for a public hearing.[160] Section 6(e) requires the Secretary to accompany standards with a statement of reasons.[161]

This statute was one of the first to combine informal rulemaking with the substantial evidence test for judicial review, which is specified by section 6(f).[162] Interpreting

[159] The feasibility limitation does not detract from the duty to take a precautionary view of the evidence. Rather, the Secretary must take feasibility considerations into account only after appraising the risk, on the basis of the best available evidence. One must keep distinct the process of determining what risk *exists* from the process of determining what risk *will be tolerated*.

[160] 29 U.S.C. § 655(b)(1)-(4).

[161] *Id.* § 655(e).

[162] *Id.* § 655(f).

this "anomalous combination,"[163] the courts reviewing standards set under section 6(b)(5), with the exception of the Fifth Circuit, have correctly perceived their role as having a dual aspect. With respect to factual issues, they must assure that the Secretary's determinations are supported by substantial evidence. But they have understood that the test cannot be interpreted to bar the Secretary from making policy judgments that the provision of informal rulemaking and the substantive mandates of the Act so clearly indicate he must make. Consequently, with respect to issues "on the frontiers of scientific knowledge,"[164] these courts have recognized that the Secretary's duty is to explain the reasoning he uses to resolve uncertainties and to show that this reasoning is consistent with the protective policies of the Act. The essential task of the courts as to these issues is to assure that the Secretary acted rationally.

The District of Columbia Circuit, Judge McGowan writing, appropriately stated the Secretary's task and the court's role in *Industrial Union Dep't, AFL-CIO* v. *Hodgson*:[165]

> From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions

[163] The combination was so characterized in Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 473 (D.C. Cir. 1974). The legislative history leading to this combination is traced in Associated Industries of N.Y.S. v. United States Dep't of Labor, 487 F.2d 342, 347-50 (2d Cir. 1973) (Friendly, J.).

[164] *Industrial Union Dep't*, 499 F.2d at 474.

[165] *Id.*

> involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis. Thus, in addition to currently unresolved factual issues, the formulation of standards involves choices that by their nature require basic policy determinations rather than resolution of factual controversies. Judicial review of inherently legislative decisions of this sort is obviously an undertaking of different dimensions.
>
> . . .
>
> Policy choices of this sort are not susceptible to the same type of verification or refutation by reference to the record as are some factual questions. Consequently, the court's approach must necessarily be different no matter how the standards of review are labeled.[166]

The court sensitively summarized the Secretary's obligation as follows:

> What we are entitled to at all events is a careful identification by the Secretary, when his proposed standards are challenged, of the reasons why he chooses to follow one course rather than another. Where that choice purports to be based

[166] *Id.* at 474-75 (footnotes omitted). In one of the footnotes the court stated: "Where existing methodology or research is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information." *Id.* at 474 n. 18, *citing* Permian Basin Area Rate Cases, 390 U.S. 747, 811 (1968).

> on the existence of certain determinable facts, the Secretary must, in form as well as substance, find those facts in the record. By the same token, when the Secretary is obliged to make policy judgments where no factual certainties exist or where facts alone do not provide the answer, he should so state and go on to identify the considerations he found persuasive.[167]

Judge McGowan's view has been cited with approval by this Court. *Federal Communications Comm'n* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 814 (1978).

Moreover, this view has been explicitly sanctioned by Congress. Congress has adopted the combination of basically informal rulemaking and the substantial evidence test in several subsequent health, safety, and environmental protection statutes.[168] An example is the 1976 Toxic Substances Control Act;[169] its legislative history on judicial review expressly endorses the approach of *Industrial Union Dep't.*[170] Congress has determined to continue using this combination in laws dealing with highly technical areas where there is substantial scientific uncertainty, even for the experts. As the District of Columbia Circuit recognized, the achievement of the Act's purposes is inseparable from and dependent on the Secretary's power to make policy judgments to resolve uncertainties, and the Secretary's actions must not be reviewed in a manner that frustrates action "where facts alone do

[167] 499 F.2d at 475-76.

[168] *E.g.*, Consumer Product Safety Act, 15 U.S.C. §§ 2056, 2060(c); Toxic Substances Control Act, 15 U.S.C. §§ 2605(c), 2618.

[169] *Id.*

[170] *See* H.R. Rep. No. 1341, 94th Cong., 2d Sess. 55-56 (1976) (House Report). The Committee paraphrased Judge McGowan's statement with approval.

not provide the answer."[171] Other courts have adopted this formulation of their review task, or have reached functionally similar formulations that require the Secretary to demonstrate the reasonableness or rationality of his policy judgments but do not block him from accomplishing the statute's purposes.[172]

Other than the Fifth Circuit, the courts have also come to understand that, at least in these highly technical subject areas, there is little, if any, meaningful difference

[171] 499 F.2d at 476.

[172] Judge Friendly's analysis in *Associated Industries* for the Second Circuit is quoted in note 173, *infra*. Also for the Second Circuit, Justice Clark adopted the District of Columbia Circuit's formulation. Society of the Plastics Industry v. OSHA, 509 F.2d 1301, 1303-04 (2d Cir. 1975), *cert. denied* 421 U.S. 992 (1975).

The Third Circuit has stated a five-part formulation of its review function. The principle ones bearing on this issue are whether the Secretary has adequately set forth his reasons, whether his reasons reflect "consideration of factors relevant under the statute," whether he considered "presently available alternatives," and, if his determination is based "in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination." Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1160 (3rd Cir. 1974). *See also* American Iron & Steel Inst. v. OSHA, 577 F.2d 825, 830-31 (3rd Cir. 1978).

Even the Fifth Circuit's formulation, although not its *practice*, is consistent with these. After reviewing these approaches, the court stated: "[I]t seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him." American Petroleum Inst. v. OSHA, 581 F.2d 493, 497 (5th Cir. 1978), *quoting from* Florida Peach Growers Ass'n v. United States Dep't of Labor, 489 F.2d 120, 129 (5th Cir. 1974). In practice, this court substituted its judgment for the Secretary's expert conclusion that quantitative risk assessments for carcinogens are too unreliable to be the basis of standard-setting.

between the substantial evidence test and the arbitrary and capricious test normally applied to rulemaking. The tests have converged to a point where any remaining theoretical distinction between them simply is not administrable.[173] The essential function of review under either test is to assure that the agency has taken into account

[173] See *e.g.*, Associated Industries of N.Y.S. v. United States Dep't of Labor, 487 F.2d 342 (2d Cir. 1973) (Friendly, J.):

> While we have felt constrained to determine and sustain the applicability of the substantial evidence test, it may well be that the controversy is semantic in some degree, at least in the context of informal rulemaking, and that it lacks the dispositional importance that respondents imply .... In WBEN, Inc. v. United States ..., while we applied to F.C.C. rulemaking the "arbitrary and capricious" standard ..., it is hard to see in what respect we would have treated the question differently if we had been applying a "substantial evidence" test .... While we still have a feeling that there may be cases where an adjudicative determination not supported by substantial evidence ... would not be regarded as arbitrary and capricious, ... in the review of rules of general applicability made after notice and comment rulemaking, the two criteria do tend to converge.

Id. at 349-50 (citations and footnotes omitted). *See also* Friendly, "*Some Kind of Hearing*," 123 U. Penn. L. Rev. 1267, 1313-14 (1975).

In Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), the court stated that which of the two tests applied would not "affect the rigorousness of our review to the extent the Government seems to suppose, or that petitioners purport to fear." *Id.* at 473. In National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975), a case arising under the Food, Drug, and Cosmetic Act, Judge Lumbard asserted outright that the two tests are identical: "In essence I think that when an agency engages in substantive rule-making, it abuses its discretion (or acts arbitrarily or capriciously) if its actions are not supported by substantial evidence." *Id.* at 705 (concurring opinion of Lumbard, J.).

(footnote continued)

the information before it and has acted rationally. And the fundamental rule under either test is that courts may not substitute their judgment for the Secretary's. *Consolo* v. *Federal Maritime Comm'n*, 383 U.S. 607, 619-21 (1966); *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474, 491 (1950); [redacted], *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 415-16 (1971).

In *Industrial Union Dep't*,[174] the court illustrated the application of these principles as follows:

> For example, in this case the evidence indicated that reliable data is not currently available with respect to the precisely predictable health effects of various levels of exposure to asbestos dust; nevertheless, the Secretary was obligated to establish some specific level as the

(footnote concluded)

The Conference Report on the 1977 Clear Air Act Amendments cites this trend, and *Associated Industries* in particular, with approval. H.R. REP. NO. 564, 95th Cong., 1st Sess. 178 (1977).

It has been suggested that the primary function of specifying the substantial evidence test with informal rulemaking may be to restrict the agency to a record. Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. Rev. 899, 935, n. 138 (1973). But even this distinction between the tests is elusive, since some recent statutes specifying the arbitrary or capricious test also provide for such a record. See § 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d). Under either review test, such a record must reflect both the factual matters at issue and the principles, hypotheses, and policies by which the agency reasons to its decision.

Thus it may be time for this Court to re-examine the assumption, expressed in Abbott Laboratories v. Gardner, 387 U.S. 136, 143 (1967), that the tests really do define different depths of judicial scrutiny of agency decisions, at least in highly technical, largely legislative areas such as these.

[174] 499 F.2d 467 (D.C. Cir. 1974).

> maximum permissible exposure. After considering all the conflicting evidence, the Secretary explained his decision to adopt, over strong employer objection, a relatively low limit in terms of the severe health consequences which could result from over-exposure. Inasmuch as the protection of the health of employees is the overriding concern of [the Act], this choice is doubtless sound, but it rests in the final analysis on an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection.[175]

This is the conclusion the Fifth Circuit should have reached.

B. The Secretary Reasonably Determined That Quantitative Risk Assessment Techniques Are Not Sufficiently Reliable To Be A Basis For Decision

In this case, the Secretary determined that techniques for quantifying cancer risk cannot yet yield estimates that are sufficiently reliable to be a basis for setting the permissible level of exposure to benzene.[176] He concluded that the exercise could not "significantly clarify the ultimate decision.[177] He stated the essential uncertainties about how chemicals cause cancer which preclude reliable quantification. He stated the problems that preclude quantitative reliance on the epidemiological studies which identify benzene as a leukemogen. There were large

[175] *Id.* at 475.

[176] 43 Fed. Reg. 5940-41 (1978). In addition, the Secretary explicitly incorporated into the benzene preamble, *id.* at 5941, his detailed consideration of the same issue in setting the coke oven emissions standard, 41 Fed. Reg. 46,742, 46,750-51 (1976).

[177] [redacted] Fed. Reg. [redacted]
43 5941.

uncertainties about the exact doses to which employees studied had been exposed. It was likely that the studies had not recorded all the cases of leukemia caused by benzene in these employees, because the full latency period may not yet have run since exposure began, and because all exposed employees have not been located and examined. There could be no quantitative estimates based on animal studies even if these estimates could be made reliably, because benzene's carcinogenicity has not yet been adequately shown in an animal test. Whether benzene interacts with other chemicals and whether it causes other cancers less readily identified and traced to a source than leukemia could not be established. Also, any reliable quantitative estimate would have to take into account benzene's effects other than cancer, some of which can also be fatal, and about which there are many similar quantitative uncertainties.[178]

For these reasons, the Secretary rejected the back-of-the-envelope calculations offered by industry witnesses and declined to generate ones of his own.[179] This decision was reasoned and well-supported. Indeed, the Secretary could not have reached any other conclusion consistent with the Occupational Safety and Health Act's mandate to take preventive action on the basis of the best available evidence.

The Fifth Circuit opinion shows that it simply failed to grasp how uncertain and imprecise the quantitative risk estimates really are. The court appears to have been misled into concluding that such techniques could pinpoint the size of the danger, when in fact they cannot even

[178] 43 Fed. Reg. 5930-32, 5940-41.

[179] *Id.* at 5940-41.

provide assurance of being within several orders of magnitude of true risks.[180]

In any event, it is not the court's role to decide de novo whether the Secretary's conclusion was correct. The court can only overturn his rejection of quantitative risk

[180] American Petroleum Inst. v. OSHA, 581 F.2d 493, 503-05 (5th Cir. 1978). In a footnote, the court referred to two particular items. *Id.* at 504 n. 23. The court cited a quantitative risk assessment performed for benzene by a unit in the Environmental Protection Agency. But this early version of the EPA document lacked a passage present in the final draft, which explains some of the heroic assumptions that the authors made concerning the substantial uncertainties. This addition undercuts the undeserved confidence the court placed in its quantitative conclusions. See the final version, EPA Carcinogen Assessment Group, Final Report On Population Risk to Ambient Benzene Exposures (with cover memorandum dated January 10, 1979).

Moreover, while a unit at EPA produces such estimates for informational purposes, the EPA Administrator has not adopted the policy of relying on these estimates in determining standards or other regulations under any of the half dozen statutes for control of chemical hazards that he administers. Thus the lower court had no basis from EPA's actions to impugn the Secretary's judgment.

The court also cited the mere averment by an economic consultant to the agency to the effect that he could do cost-effectiveness analysis, which the court stated was "an analysis which would have included some kind of risk quantification." This statement, by one who is not expert in the complex scientific issues of cancer causation, was hardly a sound basis for the court's conclusion that reliable quantitative risk assessments can be performed.

Beyond these specifics, the court appears simply to have accepted the assurances of employer's witnesses, who ignored the massive uncertainties in the techniques. The lower court adopted the term "rough" to describe the estimates it required. *Id.* at 504. This choice of terms reflects its confusion on the power of these techniques. If the court actually believed that

(footnote continued)

assessment if it can properly conclude that, under the present state of knowledge and the policies of the Act, the Secretary was irrational. In fact, the court *conceded* the Secretary's determinations were rational.[181] Thus, the lower court's decision cannot stand.

(footnote concluded)
"rough" estimates can come usefully close to the true risk, then it simply failed to comprehend the irreducible uncertainties in these techniques. If the court understood that "rough" estimates really may be off by a factor of as much as 5,000,000 (see text accompanying note 68, *supra*), then the court's conclusion that they are a useful basis for decisions was simply without logical foundation. This use of the term "rough" distorts the English language to the point of squeezing all meaning out of the word.

[181] 581 F.2d at 503.

CONCLUSION

The lower court has substituted its judgment for that of Congress and the Secretary on the proper means to protect employees from cancer and other serious diseases caused by chemicals in the workplace. The court would impose on the Secretary quantitative decision-making requirements that Congress did not mandate, and that the Secretary reasonably rejected. The decision would preclude the Secretary from taking effective preventive measures until a speculative future time when science has solved the mysteries of carcinogenesis and policy-makers have devised adequate quantitative means of making basic societal decisions. With the knowledge that this day is remote, Congress envisioned, and the Secretary has practiced, a decision making process sensitive to the qualities of the best available data and to the reality that human lives and health are at stake. The lower court would undo this. For these reasons, this Court should reverse the decision below, and remand with instructions for a decision consistent with the Occupational Safety and Health Act as outlined here.

Respectfully submitted,

RICHARD E. AYRES
DAVID D. DONIGER
Attorneys for Amicus Curiae
Natural Resources
Defense Council

May 17, 1979